

PUBLIC VERSION – CONTAINS REDACTIONS OF INFORMATION DESIGNATED HIGHLY CONFIDENTIAL

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND**

IN RE LOESTRIN 24 FE ANTITRUST
LITIGATION

MDL No. 2472

Master File No. 1:13-md-2472-S-PAS

THIS DOCUMENT RELATES TO:
Direct Purchaser Class Actions

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**DIRECT PURCHASER CLASS PLAINTIFFS' THIRD AMENDED CONSOLIDATED
CLASS ACTION COMPLAINT AND JURY DEMAND**

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Plaintiffs Ahold USA, Inc. and Rochester Drug Co-Operative, Inc. (collectively, the “direct purchaser class plaintiffs”) bring this class action, on behalf of themselves and all others similarly situated, based upon personal knowledge, the investigation of counsel, and information and belief, allege as follows:

I. INTRODUCTION

1. This civil antitrust action seeks damages arising out of (i) Warner Chilcott’s unlawful scheme to monopolize the market for oral contraceptives with 24 active tablets containing 1 mg norethindrone acetate and 20 µg ethinyl estradiol and four inactive iron tablets (the “Loestrin 24 drugs” or the “Loestrin 24 market”), and (ii) Warner Chilcott and Watson’s agreement to allocate that market and impair generic competition for branded Loestrin 24.

2. *Wrongful Orange Book listing.* Oral contraceptive products bearing the “Loestrin” name have been sold in the United States since 1973, including a formulation called Loestrin 1/20. The active pills contain relatively low doses of two hormones, norethindrone acetate and ethinyl estradiol, and are taken for 21 days. One of the known side effects of low dose birth control tablets is breakthrough bleeding or spotting. Some Loestrin products include “reminder” pills with no therapeutic value; some do not.

3. In the early 1990s, a professor at the Eastern Virginia Medical School, Dr. Gary Hodgen, tried to patent a birth control regimen that decreased the incidence of breakthrough bleeding consisting of taking the active pills in the product then commercially marketed as Loestrin 1/20 for longer than 21 days. Hodgen and his attorney made misrepresentations and omitted key information while prosecuting the patent.

4. First, the patent application cited only favorable bleeding rate data from a monkey study; Hodgen did not tell the United States Patent and Trademark Office (the “PTO”) that he himself had studied women who took active Loestrin 1/20 pills for 25 days (instead of 21 days)

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and found no significant improvement in the incidence of breakthrough bleeding. Hodgen did discuss this failed study [REDACTED]

[REDACTED]. In 1993 and 1994, before the patent issued, [REDACTED] negotiated and approved Warner Lambert's acquisition of Hodgen's patent application.

5. Second, when the patent examiner focused on the amount of ethinyl estradiol in then available oral contraceptives, Hodgen's attorney misrepresented that no commercially available oral contraceptive combination formulations contained less than 30 µg of ethinyl estradiol. In truth, Loestrin 1/20, publicly available since the 1970s and the very drug used in Hodgen's unsuccessful study, contained 20 µg of ethinyl estradiol.

6. The only explanation for (i) not disclosing the inventor's own failed study in women and (ii) not accurately representing that Loestrin 1/20 contained the same ratios and amount of active ingredients as the claimed invention is that the applicants knew the patent would never issue if they came clean.

7. In 1996, the PTO issued U.S. Patent No. 5,552,394 (the "'394 patent"). Warner Chilcott later acquired the '394 patent. On February 17, 2006, the FDA approved Warner Chilcott's application to market Loestrin 24. Warner Chilcott listed the '394 patent in the Orange Book as covering Loestrin 24.

8. *The sham litigation.* When generic manufacturer Watson sought FDA approval to market generic Loestrin 24, Warner Chilcott sued Watson for infringing the invalid and/or unenforceable '394 patent. Warner Chilcott had no realistic expectation of succeeding on the merits – the stark light of patent litigation would reveal that the '394 patent was invalid and unenforceable (whether as a result of Hodgen's misrepresentations and omissions, because Loestrin 24 does not actually reduce the incidence of breakthrough bleeding, or because earlier

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oral contraceptives containing the same amounts of active ingredients disclosed in the claims rendered the invention obvious). But Warner Chilcott nevertheless sued Watson and other generic manufacturers in hopes of delaying generic entry as long as possible.

9. *The Watson agreement.* Warner Chilcott knew that once it lost its patent lawsuit against Watson, its Loestrin 24 product would fall off the “patent cliff” – Watson’s generic product would quickly take 85% or more of the unit sales. This competition would save hundreds of millions of dollars for the direct purchaser class plaintiffs and other purchasers of Loestrin 24. In order to forestall this competition and consequent loss of sales, Warner Chilcott paid Watson to delay marketing its generic Loestrin 24. Under the guise of settling the patent lawsuit, Watson agreed to keep its generic Loestrin 24 off the market until January 2013, and, in exchange, Warner Chilcott agreed to pay Watson at least [REDACTED] million. These payments included:

- a. A promise not to market a competing authorized generic (“AG”) version of Loestrin 24 during the first 180 days that Watson’s generic Loestrin 24 was on the market (worth at least \$41.34 million to Watson);¹
- b. A promise not to grant a license to any other generic to enter the market until at least six months after Watson had entered;
- c. Above-market-rate payments to Watson to help market another Warner-Chilcott product, Femring (worth about [REDACTED] to Watson); and
- d. An agreement to provide Watson with licensing rights to another Warner Chilcott product, Generess Fe, at below market rates (worth [REDACTED] to Watson).

10. To shore up its market allocation agreement with Watson, Warner Chilcott

¹ A no-authorized-generic (“no-AG”) agreement is a type of market allocation agreement in which a brand manufacturer pays a first-filer generic manufacturer to delay the launch of its generic by agreeing not to compete by withholding an AG (basically the brand drug product marketed and priced as a generic), during either the first-filer generic manufacturer’s first 180 days on the market or some other period. In such an arrangement, the value to the generic manufacturer is the opportunity to be the only generic on the market during those first 180 days, allowing the generic manufacturer to (i) obtain all generic sales during that time, instead of splitting the sales 50-50 with an AG, and (ii) charge a higher price for the generic in the absence of competition from the AG.

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entered into agreements with later generics Lupin and Mylan.² Both agreed to delay their launches until six months after Watson launched, promising not to launch until the '394 patent expired.

11. *The product hop.* By the time the delayed entry dates finally arrived, Warner Chilcott had “hopped” the market from Loestrin 24 to another product: Minastrin 24. Warner Chilcott reformulated Loestrin 24 into Minastrin 24, with the purpose and effect of preventing generic Loestrin 24 from being substitutable for the “new” product at the pharmacy counter.

12. Minastrin 24 is Loestrin 24 with two minor tweaks: Warner Chilcott made what the FDA termed “insignificant manufacturing changes” to the active pills and added spearmint and a sweetener to the inactive “reminder” pills. Warner Chilcott did not do anything to make the *active* Loestrin pills more palatable, as it did not add sweeteners or flavors to them. Warner Chilcott simply tinkered with the flavoring of the “reminder” pills and changed the label to say that women could chew all the pills. After it had obtained a three-year marketing exclusivity based on the new chewable form, Warner Chilcott amended the label to say that women could, if they wanted, swallow the pills instead.

13. The modifications Warner Chilcott made to Loestrin 24 to create Minastrin 24 had no meaningful safety, efficacy, or other benefit for patients. The tweaks did, however, mean that less expensive generic Loestrin 24 could not be substituted for Minastrin 24 at pharmacies. A pharmacist presented with a prescription for Loestrin 24 can automatically substitute a less expensive AB-rated generic version of Loestrin 24. But if presented with a prescription for Minastrin 24, a pharmacist could not fill the prescription with generic Loestrin 24. The trivial

² Lupin Pharmaceutical, Inc., Lupin Ltd., and Mylan, Inc.

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tweaks that Warner Chilcott made to Loestrin 24 to turn it into Minastrin 24 had the intentional effect of frustrating and thwarting the normal process of generic substitution.

14. Once the FDA approved Minastrin 24, Warner Chilcott employed its army of sales force detailers to cannibalize the Loestrin 24 prescriptions, *i.e.*, to aggressively switch them to the new product. Then, in July 2013, Warner Chilcott strategically discontinued sales of Loestrin 24 to coerce doctors to switch patients to Minastrin 24 before generic Loestrin 24 entered the market. By the time generic versions of Loestrin 24 finally entered the market in 2014, they made far fewer sales because Warner Chilcott had switched the prescription base to Minastrin 24.

15. *The direct purchasers' injuries.* But for the anticompetitive scheme and Watson agreement, a generic version of Loestrin 24 would have been available as early as September 2009, when the FDA granted final approval to Watson's generic Loestrin 24. Other generic versions of Loestrin 24, including an AG version marketed directly or indirectly by Warner Chilcott, would also have entered simultaneously, driving generic prices down to near marginal cost. The direct purchaser class plaintiffs and members of the class would have substituted the less expensive generic products for their purchases of more expensive branded Loestrin 24. Instead, as a result of defendants' unlawful conduct, plaintiffs and all members of the direct purchaser class suffered injuries in the form of overcharges.

II. PARTIES

16. Plaintiff Ahold USA, Inc. ("Ahold") is a Maryland corporation with its principal place of business located at 1385 Hancock Street in Quincy, Massachusetts. Ahold brings this action as an assignee of McKesson Corporation ("McKesson"). During the class period, McKesson purchased branded Loestrin 24 and Minastrin 24 directly from Warner Chilcott at supracompetitive prices; Ahold purchased branded Loestrin 24 and Minastrin 24 from McKesson

at supracompetitive prices and has thereby been injured. Ahold also purchased generic Loestrin 24 directly from Amneal during the class period.

17. Plaintiff Rochester Drug Cooperative, Inc. (“RDC”) is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business located at 50 Jet View Drive, Rochester, New York 14624. During the class period, RDC purchased branded Loestrin 24 and Minastrin 24 directly from Warner Chilcott at supracompetitive prices and has thereby been injured. RDC also purchased generic Loestrin 24 directly from generic manufacturers during the class period.

18. The defendants’ names and the corporate relationships between and among them have changed over time due to consolidation in the pharmaceutical industry. During much of the wrongdoing at issue in this case, the brand company interests of the Warner Chilcott entities and the generic company interests of the Watson entities were separate. More recently, these companies have become part of the same multinational corporation: Allergan plc.

19. Defendant Warner Chilcott Company, LLC (formerly known as Warner Chilcott Company, Inc.) is a limited liability company organized and existing under the laws of Puerto Rico, with its principal place of business at Road 195, Km. 1.1, Union Street, Fajardo, Puerto Rico. It maintains a place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866. Warner Chilcott Company, Inc. was a party to the Watson agreement. Warner Chilcott Company, LLC is the current assignee of the ’394 patent. Warner Chilcott Company, LLC holds an approved NDA from the FDA for a formulation of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 µg) tablets and four ferrous fumarate tablets, which it sells throughout the United States under the brand name Loestrin 24. Warner Chilcott Company is a wholly owned subsidiary of Warner Chilcott plc.

20. Defendant Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866. Warner Chilcott (US), LLC helped pursue applications for FDA approval of Loestrin 24 and Minastrin 24 and holds NDCs for Loestrin 24.

21. Defendant Warner Chilcott Sales (US), LLC is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866. Warner Chilcott Sales (US) markets pharmaceuticals in the United States and also helped pursue applications for FDA approval of Loestrin 24 and Minastrin 24.

22. The foregoing defendants are collectively referred to as “Warner Chilcott.”

23. Defendant Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, with its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories, Inc. is a wholly owned subsidiary of Watson Pharmaceuticals, Inc., which, in 2013, became Actavis, Inc. Watson Laboratories, Inc. and Watson Pharmaceuticals, Inc. are parties to the Watson agreement.

24. Defendant Actavis, Inc. is a company organized and existing under the laws of Nevada, with its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054.

25. Actavis, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. are collectively referred to as “Watson.” Watson is engaged in the worldwide marketing, production, and distribution of generic pharmaceutical products, including in this judicial district.

26. On or about January 24, 2013, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. and continued the merged operations under the name Actavis, Inc.

27. On or about October 1, 2013, Actavis, Inc. acquired Warner Chilcott plc³ and continued the merged operations under the name Actavis plc.

28. In March 2015, Actavis plc acquired Allergan plc and, in June of 2015, announced that it would change its name to Allergan plc. Allergan plc markets branded and generic pharmaceuticals throughout the United States and has commercial operations in the United States and approximately 100 countries around the world.

29. Defendant Allergan plc is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. Allergan plc maintains a place of business within the United States at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

30. All of the defendants' actions described in this complaint are part and in furtherance of the unlawful conduct alleged herein and were authorized, ordered, and/or done by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or those of their predecessors-in-interest) within the course and scope of their duties and employment and/or with the defendants' actual, apparent, and/or ostensible authority.

III. JURISDICTION AND VENUE

31. This action alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and seeks relief under section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Ahold, RDC, and members of the direct purchaser class resulting from the defendants'

³ Warner Chilcott plc is a public limited company incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. It maintains a place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866. Though not named as a defendant, it was a parent company of the other Warner Chilcott entities at the time of the Actavis merger.

conspiracy to restrain trade in the United States in the Loestrin 24 market. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a) & 1407 and 15 U.S.C. § 15.

32. Venue is proper in this district pursuant to 15 U.S.C. §§ 15(a) & 22 and 28 U.S.C. §§ 1391(b)-(d) because during the class period the defendants resided, transacted business, were found, or had agents in this district and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district.

33. The defendants' conduct was within the flow of and was intended to and did have a substantial effect on the interstate commerce of the United States, including in this district.

34. During the class period, Warner Chilcott manufactured, sold, and shipped Loestrin 24 and Minastrin 24 in interstate commerce. The conspiracy in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

35. During the class period each defendant, or one or more of its affiliates, used instrumentalities of interstate commerce to join or effectuate their conspiracy.

36. This Court has personal jurisdiction over each defendant because each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at and have had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The regulatory structure for approval and substitution of generic drugs.

37. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain approval from the Food and Drug Administration ("FDA") to sell

the product by filing a New Drug Application (“NDA”).⁴ An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.⁵

38. When the FDA approves a brand manufacturer’s NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”) any patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.⁶

39. The FDA relies completely on the brand manufacturer’s truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer’s patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman amendments

40. The Hatch-Waxman amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.⁷ A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA and must further show that the generic contains the same active ingredient(s), dosage form, route of

⁴ 21 U.S.C. §§ 301-392.

⁵ 21 U.S.C. §§ 355(a) & (b).

⁶ 21 U.S.C. §§ 355(b)(1) & (c)(2).

⁷ See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand. The FDA assigns generics that meet these criteria relative to their brand counterparts an “AB” rating.

41. The FDCA and Hatch-Waxman amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.⁸ Nonetheless, even drugs that are bioequivalent, but which do not share the same dosage form, are not AB-rated to one another. To be AB-rated, a bioequivalent drug must be of the same dosage form. Under the AB-rating system, a tablet that is approved as “chewable” is not AB-rated to a tablet that is not approved as chewable, even though the drugs may be entirely bioequivalent.

42. Through the Hatch-Waxman amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers’ incentives to create new and innovative products.

43. The Hatch-Waxman amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all

⁸ 21 U.S.C. § 355(j)(8)(B).

did. In 1984, prescription drug revenues for brands and generics totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$329.2 billion, with generics accounting for 86% of prescriptions.⁹ Generics are now dispensed 95% of the time when a generic form is available.¹⁰

2. ANDA paragraph IV certifications.

44. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman amendments, a generic manufacturer's ANDA must contain one of four certifications:

- a. That no patent for the brand has been filed with the FDA (a “paragraph I certification”);
- b. That the patent for the brand has expired (a “paragraph II certification”);
- c. That the patent for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a “paragraph III certification”); or
- d. That the patent for the brand is invalid or will not be infringed by the generic manufacturer's proposed product (a “paragraph IV certification”).¹¹

45. If a generic manufacturer files a paragraph IV certification, a brand manufacturer has the ability to delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed

⁹ See IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the U.S. in 2013*, at 30, 51 (Apr. 2014).

¹⁰ *Id.* at 51.

¹¹ 21 U.S.C. § 355(j)(2)(A)(vii).

by the generic manufacturer's ANDA.¹² Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30 month stay.

3. Patents are not bulletproof.

46. Patents are not bulletproof. Patents are routinely invalidated or held unenforceable, either upon reexamination by the PTO, by court decision, or by jury verdict. A patent holder at all times bears the burden of proving infringement.

47. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable. For example, a patent is invalid or unenforceable when the disclosed invention is obvious in light of earlier prior art. A patent is also invalid or unenforceable when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution.

48. In those circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on

¹² 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a "30-month Hatch-Waxman stay" or "30-month stay." The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

the merits of a patent infringement suit.

49. As a statistical matter, if the parties litigate to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.¹³ An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.¹⁴

4. The first filer's 180-day exclusivity period.

50. Generics may be classified as (i) first-filer generics, (ii) later generic filers, or (iii) authorized generics.

51. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman amendments grant the first paragraph IV generic manufacturer ANDA filer ("first filer") a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.¹⁵ That is, when a first filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first generic has been on the market for 180 days, or until its first-filer exclusivity has been forfeited.

¹³ FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at vi-vii (July 2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

¹⁴ John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

¹⁵ 21 U.S.C. § 355(j)(5)(B)(iv) & (D).

52. The 180-day window is referred to as the first filer’s six-month or 180-day “exclusivity,” though it is a bit of a misnomer, because a brand manufacturer (such as Warner Chilcott) can launch an AG version of its own brand under its own NDA at any time, and brand manufacturers frequently do so in response to generic entry in order to recoup some of the sales they would otherwise lose.

53. The Supreme Court has recognized that “this 180-day period of exclusivity can prove valuable, possibly ‘worth several hundred million dollars’” to the first filer.¹⁶

54. A first filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

55. Amendments to Hatch-Waxman provide that a first filer forfeits its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA.

B. The competitive effects of AB-rated generic competition.

56. Generics contain the same active ingredient(s) and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is their price. Because generics are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 10% less expensive than their brand counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are

¹⁶ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).

multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers.

57. Since the passage of the Hatch-Waxman amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. In a recent study, the Federal Trade Commission (“FTC”) found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.¹⁷ As a result, competition from generics is viewed by brand manufacturers, such as Warner Chilcott, as a grave threat to their bottom lines.

58. Generic competition enables all direct purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price.

59. Until a generic version of the brand enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue to profitably charge supracompetitive prices. Brand manufacturers, such as Warner Chilcott, are well aware of generics’ rapid erosion of their brand sales. Brand

¹⁷ See FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> (“FTC Pay-for-Delay Study”).

manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

1. The first AB-rated generic is priced below the brand.

60. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.¹⁸ Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and AB-rated generic combined).

61. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (the brand's AG can be, and often is, on the market during the 180-day exclusivity period). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later generics drive prices down further.

62. Once generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.¹⁹

63. According to the FDA and the FTC, the greatest price reductions are experienced

¹⁸ FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at ii-iii, vi, 34 (Aug. 2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf> ("FTC 2011 AG Study"); FTC Pay-for-Delay Study at 1.

¹⁹ See, e.g., Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & Econ. 311 (2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market – 18 Years after the Waxman-Hatch Act* (Univ. of Miami, Dep't of Econ., Working Paper, 2004); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993 (2007).

when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic results in a near term retail price reduction of around 10% as compared to the brand price, but that with two generic entrants the near term retail price reduction is about 50%.

64. In a report by the FTC issued at the request of Congress in 2011, the FTC found that generics captured 80% or more of sales in the first six months.²⁰ In the end, total payments to the brand manufacturer decline to a small fraction of the amounts paid before generic entry. This is so because, “[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.”²¹

3. Authorized generics, like other generics, compete on price.

65. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer’s subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand in a different package.

66. One study notes that “pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed ‘authorized generics.’”²²

67. Brand manufacturers sometimes begin selling AGs before the first-filer generic

²⁰ FTC 2011 AG Study at 66-67.

²¹ See *Generic Drugs: Questions and Answers*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm> (last visited May 9, 2016).

²² Kevin A. Hassett & Robert J. Shapiro, Sonecon, LLC, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, at 3 (May 2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

enters the market in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

68. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period, when no other ANDA generic can be on the market). A study analyzing three examples of AGs found that “[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand.”²³

69. The FTC found that AGs capture a significant portion of sales, reducing the first-filer generic’s revenues by approximately 50% on average.²⁴ The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

C. Pharmaceutical manufacturers game the regulatory structure in order to impair competition.

70. When they do not face generic competition, brand manufacturers can usually sell the brand far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power. When generics enter the market, however, they quickly take 90% or more of the unit sales. And when multiple generics are in the market, the competition between the generics drives their prices to near the marginal cost of production.

²³ Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, 26 Health Affairs 790, 796 (2007).

²⁴ FTC 2011 AG Study at 139.

This competition puts an end to the brand manufacturer's market power and delivers enormous savings to drug purchasers.

71. Brand and generic manufacturers have a collective interest in preventing this competition from breaking out. If they work together to prevent or delay competition, they can keep the profit margins on all of the unit sales at 70% and split the resulting excess profits among themselves. They can keep for themselves the enormous savings that competition would have delivered to drug purchasers.

72. A brand manufacturer in the marketplace without competition from generics gets all of the profits on all of the unit sales.

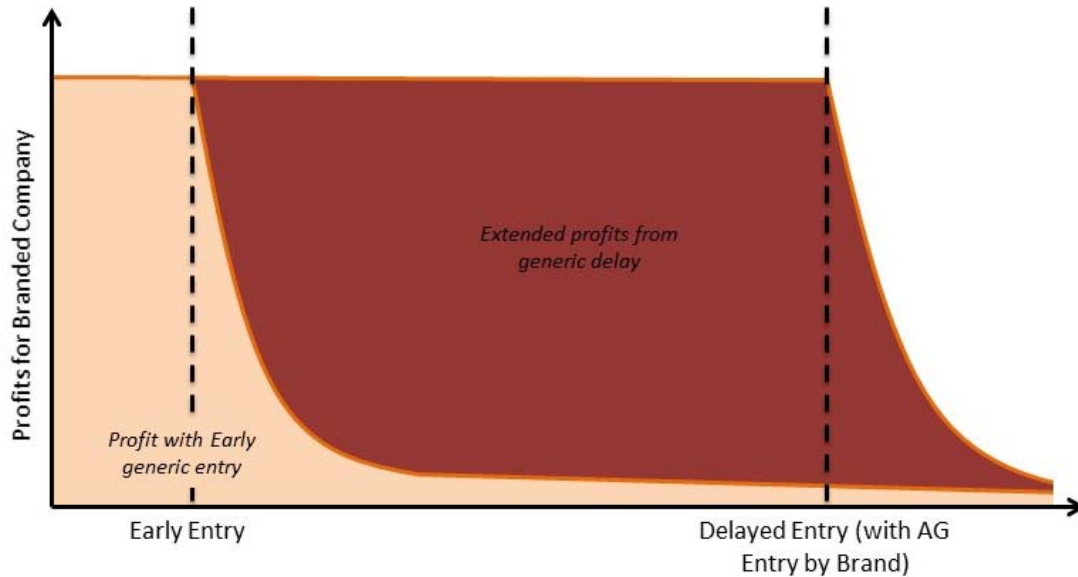
73. When generic entry occurs, the brand manufacturer loses most of the unit sales; generic manufacturers sell most of the units, but at drastically reduced prices; and competition delivers enormous savings to consumers. Competition converts what formerly were excess profits into purchaser savings.

74. To prevent this from happening, brand and generic manufacturers sometimes – unlawfully – agree to not compete and instead split the purchaser savings between themselves.

75. Figure 1 compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (*i.e.*, with only an agreed entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (*i.e.*, while the litigation is still pending) or prevails in the patent litigation and then launches

its product.

Figure 1. Impact of Generic Delay on Brand Profits



76. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide the purchaser savings between themselves. The generic manufacturer will not refrain from competing if it does not share in the ill-gotten gains through some means. Pay-offs from the brand manufacturer are the means by which brand and generic manufacturers divide between themselves the ill-gotten gains that delayed competition makes possible. These unlawful pay-off deals are often referred to as “pay-for-delay,” “exclusion payment,” or “reverse payment” agreements.

77. It is often necessary for the brand manufacturer to pay off only the first generic manufacturer that included a paragraph IV certification in its ANDA (the so-called first filer). The first filer’s agreement to delay marketing its drug also prevents other generic manufacturers from marketing their products.

78. Later ANDA filers have more modest financial expectations because they have no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been or is on its way to being commoditized.

79. In the absence of an anticompetitive agreement between the brand company and the first filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

80. When an anticompetitive agreement with the first filer is already in place, however, pursuing the litigation to conclusion becomes less attractive to later filers. The later generic manufacturers know that the first filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment settlement). The later generics have to bear the brunt of the litigation costs themselves and, upon prevailing in the patent litigation, expect to face competition from at least the first-filer generic, and typically an authorized generic as well, despite having expended time and resources litigating the infringement case. The first settlement between a brand and first-filer generic (such as the Watson agreement at issue here) will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first filer, the first filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

81. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic and agree to drop their challenges to

the brand manufacturer's patent(s) and stay off the market until after entry by the first filer.

82. Exclusion payment agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

1. No-AG clauses provide a means for manufacturers to share the gains from conspiring.

83. In the 1990s, the pay-offs from brand manufacturers often took the form of cash payments to the generic competitor. Since the 2000s, as a result of regulatory scrutiny, congressional investigations, and class action lawsuits, brand and generic manufacturers have entered into increasingly more elaborate agreements in an attempt to hide the pay-offs.

84. One form of pay-off at issue in this case is a no-AG clause. Pursuant to a no-AG clause, the brand manufacturer agrees not to market an AG version of the brand drug for some period of time after the first generic enters.

85. The first filer's ANDA exclusivity does not prohibit the brand manufacturer from marketing its *NDA-based* AG. The Hatch-Waxman amendments' 180-day marketing period is "exclusive" only as against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

86. Absent a no-AG clause, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or weeks or months before) the first generic enters the marketplace. But competition from an AG has a drastically negative effect on the first-filer generic's revenues. Competition from an AG typically cuts the first filer's revenues by more than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower – delivering commensurate savings to drug purchasers.

87. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by not competing with an AG. The brand manufacturer gains from the delayed onset of generic competition. The first filer gains from the absence of generic competition for the first 180 days of marketing. And drug purchasers lose – first by the delay in the onset of generic competition, and then by the absence of AG competition once generic entry finally occurs.

88. The brand and first filer's reciprocal pledges not to compete harm purchasers thrice over. The pact delays the first filer's entry into the marketplace and thereby extends the time during which the brand is the only product on the market. By delaying the first filer's entry, the pact also delays the time when other generics enter. And the pact prevents the brand from marketing an AG during the 180-day exclusivity period, reducing price competition during that period, particularly price competition that would otherwise occur between the first filer's generic and the brand's AG.

89. For the first filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-AG pledge thus has the same economic effect as a pay-off made in cash. As explained by the then-Chairman of the FTC:

Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you \$200 million." Now, the brand might say to the generic, "if I

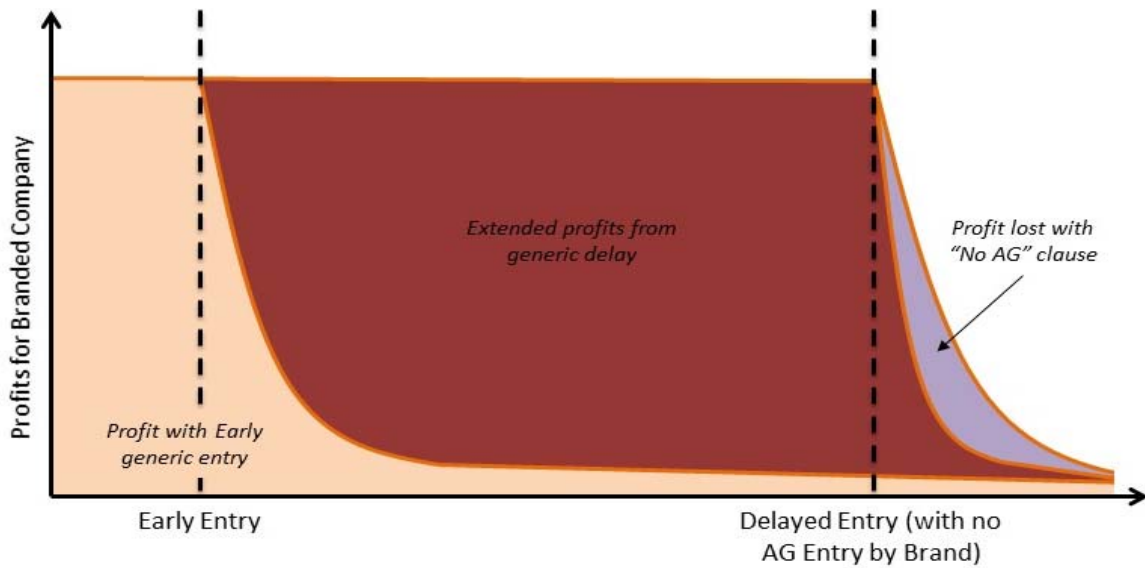
launch an AG, you will be penalized \$200 million, so why don't you go away for a few years and I won't launch an AG.”²⁵

90. For a first filer (like Watson) of a brand with hundreds of millions of dollars in annual sales (like Loestrin 24), the difference between selling a generic without having to compete against an AG and selling in competition with an AG can amount to many millions of dollars. These economic realities are well known in the pharmaceutical industry. No-AG agreements like the one between Warner Chilcott and Watson thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

91. Figure 2 depicts what happens when a settlement agreement includes a no-AG promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (*i.e.*, shares with the generic).

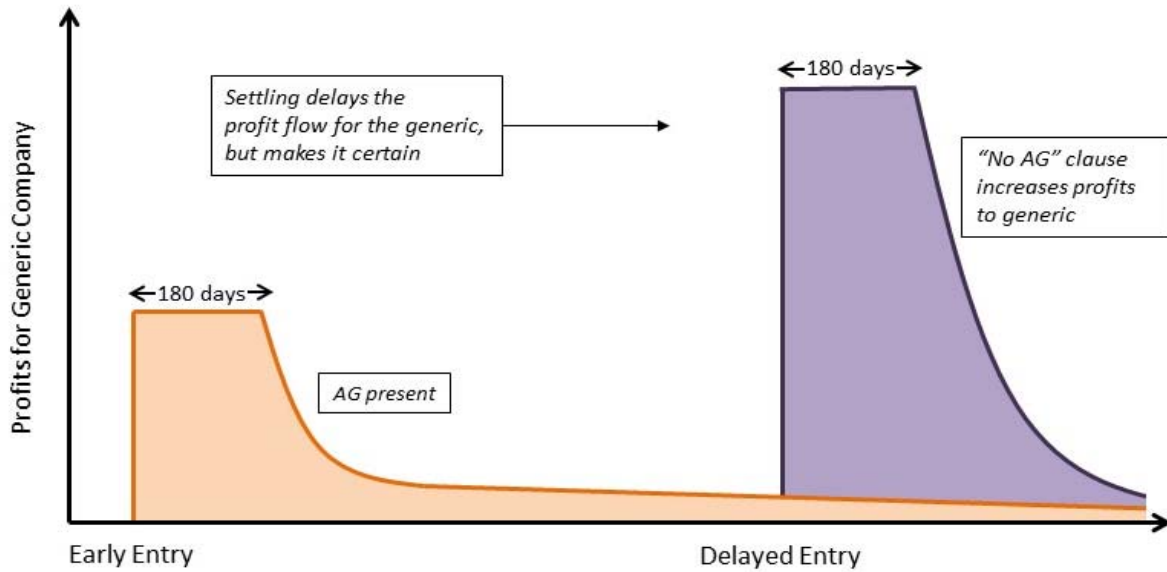
²⁵ *Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics*, (June 2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.pdf>.

Figure 2. Impact of No-AG Clause on Brand Profits



92. Figure 3 depicts the generic manufacturer’s principal considerations in deciding whether to accept a no-AG settlement. Without a settlement, the generic could enter earlier – either when the 30-month stay expires (“at risk”) or when it wins the litigation. The generic manufacturer’s profits (gross margins) would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (i) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent and (ii) it is expected that the brand manufacturer will launch an authorized generic. With a no-AG promise, the profit flow occurs later but is more certain and is larger – roughly twice the size – because the generic manufacturer does not lose half of the market to the brand manufacturer’s authorized generic can charge a higher price.

Figure 3. Impact of No-AG Promise on Generic's Profits



93. Pay-offs by means of no-AG clauses usually exceed the value that the first filer could have obtained *even if it had won* the patent infringement litigation. During the first six months the first filer typically makes 80% of all the profits it will ever make on the product. As a reward for challenging the patent, the Hatch-Waxman amendments provide the first filer a period of 180 days of ANDA exclusivity. But the Hatch-Waxman amendments do not prevent the brand manufacturer from marketing an authorized generic during that time, and the brand manufacturer would market an authorized generic if the generic manufacturer entered the market after gaining final approval. By settling the patent case in exchange for a no-AG pay-off, the first filer converts that critical six months into a period of total generic exclusivity, thus doubling its unit sales and making those sales at a higher price.

2. Brand manufacturers use anticompetitive product hops.

94. Another way that brand manufacturers impair generic competition is by preventing the generic from being AB-rated to the brand drug and thereby impairing generic substitution. The AB-rating requirement for generic drugs is designed to ensure therapeutic equivalence to the reference product. It is concerned only with safety and efficacy and not with effects on competition.

95. FDA regulations permit brand manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. An unscrupulous brand manufacturer that anticipates the onset of generic competition to its drug can modify the dosage form, strength, or some other characteristic of its product from, say, A to A₁, for the purpose of preventing the anticipated generic product from being A-B rated to the “new” brand product. Before the generic manufacturer receives FDA approval for the generic version of brand drug A and enters the market, the brand manufacturer can get approval for brand drug A₁ and then cannibalize the sales of brand drug A – *i.e.*, use its massive sales force to get doctors to switch their prescriptions from A to A₁. Thus, before the generic of brand A enters the market the brand manufacturer will have: (i) ensured that the generic product cannot be AB-rated to, and substitutable for, brand A₁; and (ii) switched the prescription base from A to A₁. Consequently, when the generic for brand drug A finally gets FDA approval to enter the market, it will garner few sales as a generic because it is not substitutable for the new brand product to which the prescription base has been switched.

96. The timing of the product hop is critical. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the brand follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would

make ten times more sales of its brand follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that “it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity.”²⁶ Industry analysts in the United States have reached the same conclusion, warning brand manufacturers it is essential that they switch patients to the new formulation before the generic enters.

97. It is equally well known that, after a product hop, doctors are unlikely to prescribe the original product – in this case, Loestrin 24. Having switched their prescribing habits from the original to the reformulated product – and having switched specific patients’ medications from the original to a reformulated product – most doctors will not switch their prescribing habits or their patients back to the original product after the generic is available. And pharmacists are unable to combat the hop through the efficient mechanism of automatic substitution because the dosage form and/or dosage amount is different. Thus, in most instances, the generic’s opportunity to compete for those original brand sales is gone forever.

98. Brand manufactures know that, if they successfully cannibalize the original product’s sales before the generics enter the market, the generics may not *ever* come to market. Automatic substitution at the pharmacy counter is a generic’s only cost-efficient means of competing. Costs incurred to encourage a doctor to write a prescription for a particular company’s generic would be squandered because the pharmacist can fill the prescription with a competitor’s AB-rated generic. And this is a good thing. If a generic manufacturer could

²⁶ European Commission, *Pharmaceutical Sector Inquiry Final Report*, at 356 (July 8, 2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

profitably market the product to doctors on a basis other than price, this would merely replicate the price-disconnect failure in these markets. The price disconnect is the problem impeding cost-efficient competition, and AB-rated substitution at the pharmacy counter is the cure.

V. STATEMENT OF FACTS

A. The FDA approves Warner Chilcott's Loestrin 24.

1. Loestrin's active ingredients have been used to prevent pregnancy since the 1970s.

99. Traditional oral contraceptives contain 21 active pills, taken once a day for 21 days. Many oral contraceptives include 7 inactive iron pills.

100. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. In fact, norethindrone and ethinyl estradiol have served as active ingredients in oral contraceptives bearing the "Loestrin" name since the early 1970s.

101. On April 30, 1973, the FDA simultaneously approved NDAs for Loestrin Fe 1.5/30 and Loestrin 1/20 as methods of oral contraception in women.²⁷ Both provide a continuous dosage regimen consisting of 21 active pills containing norethindrone acetate and ethinyl estradiol.²⁸

102. Both Loestrin 1.5/30 and Loestrin 1/20 include seven inactive "reminder" iron pills that – according to the label – do not serve any therapeutic purpose; they are present only to

²⁷ For all Loestrin products, the "Fe" is sometimes dropped from the name. "Loestrin Fe 1/20" and "Loestrin 1/20" refer to the same product. "Loestrin 24 Fe" and "Loestrin 24" refer to the same product.

²⁸ The active pills in Loestrin 1.5/30 are pink and contain 1.5 mg norethindrone acetate and 30 µg ethinyl estradiol. The active pills in Loestrin 1/20 are yellow and contain 1 mg norethindrone acetate and 20 µg ethinyl estradiol. The numerators in the fractions in the Loestrin drug products' names refer to the number of milligrams of norethindrone acetate contained in an active tablet. The denominators refer to the number of micrograms of ethinyl estradiol contained in an active tablet.

facilitate ease of drug administration via a 28-day regimen.²⁹

103. There is a question as to whether giving women iron tablets helps combat the potential anemia sometime associated with menstruation. But it should not be assumed that all patients desiring an oral contraceptive agent are anemic; administering iron when it is not needed can lead to iron poisoning.

104. On October 1, 1976, the FDA approved two additional Loestrin formulations, Loestrin 21 1.5/30 and Loestrin 21 1/20. Loestrin 21 1/20 is known as “Loestrin 21”. The Loestrin 21 1.5/30 and Loestrin 21 formulations include only 21 active tablets. The patient takes one tablet daily for 21 consecutive days followed by one week of no tablets. This is described as “three weeks on – one week off.”

105. Loestrin 1/20 and Loestrin 21 both contain 21 of the same active tablets. The only difference is that the Loestrin 21 pack does not contain any inactive tablets.

106. Loestrin 1.5/30 and Loestrin 21 1.5/30 both contain the same active tablets. The only difference is that the Loestrin 21 1.5/30 pack does not contain any inactive tablets.

107. Generic versions of all four first-generation Loestrin products have been available for decades. Defendant Watson sells, or used to sell, FDA-approved generic versions of all four products.

2. The active pills in Loestrin 24 are the same as those in Loestrin 1/20 and Loestrin 21.

108. On April 15, 2005, Warner Chilcott submitted NDA 21-871 seeking FDA approval to market what became known as Loestrin 24. The FDA approved the NDA on February 17, 2006.

²⁹ The terms placebo, inactive pills, reminder pills, and iron pills are used interchangeably.

109. Loestrin 24 contains 24 active tablets (containing 1 mg of norethindrone acetate and 20 µg of ethinyl estradiol) and 4 placebo tablets (containing ferrous fumarate).

110. Loestrin 24 contains the same active tablets as Loestrin 1/20 and Loestrin 21. Loestrin 24 contains 24 active tablets in each pack (instead of 21).

111. The labeling for Loestrin 24 refers to the inactive tablets as “reminder” pills. It instructs patients to “THROW AWAY” the reminder pills they missed if they forget to take one.

112. Warner Chilcott earned over \$1.75 billion in revenue from branded Loestrin 24 sales through the end of 2012.

Year	Annual Revenue ³⁰
2012	\$389 million
2011	\$396 million
2010	\$342 million
2009	\$247 million
2008	\$197 million
2007	\$148 million
2006	\$ 44 million

B. Warner Chilcott lists the '394 patent in the Orange Book as covering Loestrin 24, despite knowing it is invalid or unenforceable.

113. On April 15, 2005, as part of its NDA filings, Warner Chilcott identified the '394 patent as covering Loestrin 24 or a method of using Loestrin 24. Warner Chilcott told the FDA that the '394 patent expired on July 22, 2014.

³⁰ Reflects IMS data for branded Loestrin 24 sales only.

114. The purported invention described in the '394 patent is a method of oral contraception characterized by a reduced incidence of breakthrough bleeding that comprises administering the claimed combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle.

115. Loestrin 24 is the purported commercial embodiment of the '394 patent.

116. Before listing the '394 patent, Warner Chilcott knew that it was invalid and/or unenforceable. Warner Chilcott listed the patent in order to interfere with its generic competitors' ability to bring less expensive versions of Loestrin 24 to market.

1. The '394 patent application and issuance.

117. On July 22, 1994, Dr. Gary Hodgen – a professor at the Eastern Virginia Medical School ("EVMS")³¹ – applied for a patent for a method of female contraception *characterized by a reduced incidence of breakthrough bleeding* by administering a combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle in which the daily amounts of estrogen and progestin are equivalent to about 5-35 µg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate. Hodgen assigned the application to his employer, EVMS.

118. The title of the patent is "Low Dose Oral Contraceptives *with Less Breakthrough Bleeding* and Sustained Efficacy."³²

119. Breakthrough bleeding, also referred to as spotting or intermenstrual bleeding, refers to vaginal bleeding that occurs mid-cycle, as opposed to during menstruation. Breakthrough bleeding is a common but annoying and potentially embarrassing side effect associated with many oral contraceptives. It is thought to occur more often when women start

³¹ Formerly called the Medical College of Hampton Roads.

³² All emphasis added unless otherwise specified.

taking an oral contraceptive or switch oral contraceptives. Breakthrough bleeding generally is greatest in the first three to four months after starting an oral contraceptive, and it steadily declines and typically stabilizes by the end of the fourth cycle.

120. The patent specification states, “[i]t is the object of the present invention to provide a new estrogen-progestin combination and regimen for oral contraceptive use which maintains the efficacy and *provides enhanced control of endometrial bleeding.*”

121. Claim 1 recites:

A method of female contraception which is characterized by a reduced incidence of breakthrough bleeding after the first cycle which comprises monophasically administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the daily amounts of estrogen and progestin are equivalent to about 1-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively, and in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate.

Claims 2-12 all depend on Claim 1.

a. The PTO is told about a supportive monkey study.

122. In support of the claim that a 24-day regimen reduced breakthrough bleeding, Hodgen submitted minimal data from a study in ten monkeys.

123. Decades after the original Loestrin products were approved, Hodgen and other scientists at EVMS conducted a study in monkeys to determine whether administering Loestrin 1/20 active tablets for longer than the recommended 21 days decreased the incidence of breakthrough bleeding.

124. In 1992, ten adult female Cynomolgus monkeys were divided into two groups. These monkeys experience menstrual cycles similar to women. The scientists took commercially available Loestrin 1/20 active tablets and ground them into a powder. They then “adjusted” the medication to fit the smaller body weight of the monkeys. Five monkeys received

an ultra-low dose oral contraceptive for 21 consecutive days, followed by seven non-treatment days. Five monkeys received an ultra-low dose oral contraceptive for 24 consecutive days, followed by four non-treatment days. Each group was treated for three cycles. The study ostensibly showed a decrease in the incidence of breakthrough bleeding in cycles 2 and 3 in monkeys in the 24-day treatment group.

125. Given the small number of monkeys in the study, the difference between a statistically significant results ($p < 0.05$) and a not statistically significant result ($p > 0.05$) is quite small. If a scientist had noticed breakthrough bleeding in additional monkeys in the 21-day treatment group, or missed breakthrough bleeding in monkeys in the 24-day treatment group, the study may not have shown that the 24-day treatment group had significantly less breakthrough bleeding than the 21-day treatment group.

b. The PTO did not know about a failed study in women.

126. The PTO did not know that a human study – conducted by Hodgen – showed no statistically significant differences in bleeding between women taking the active tablets in Loestrin 1/20 for 25 days and women taking the active tablets in Loestrin 1/20 for 21 days.

127. Beginning on or around January 1993, scientists at the EVMS began the human study where women took Loestrin 1/20 active tablets for 25 consecutive days of the 28-day cycle.

128. In 1993, Loestrin 1/20 was commercially marketed by Parke-Davis of Morris Plains, NJ (the marketing arm of Warner Lambert).

129. In the study, thirty healthy females (ages 22 to 35) were randomized to one of two low dose oral contraceptive regimens. All patients were non-smokers on no hormonal medications and had regular menstrual cycles without breakthrough bleeding. The 15 patients in Group A received a monthly regimen of 25 consecutive Loestrin 1/20 tablets followed by three

placebo tablets. The 15 patients in Group B received a conventional regimen of 21 Loestrin 1/20 tablets followed by 7 placebo tablets. Each group was treated for three months.

130. The study participants knew they were taking Loestrin 1/20 tablets. Those in Group A knew they were taking Loestrin 1/20 tablets for 25 consecutive days of the 28-day cycle. Participants were not obligated to keep the study design or methods confidential.

131. Each subject self-reported bleeding patterns in a daily calendar.

132. The scientists compared the two groups with respect to bleeding patterns. *The scientists did not find any significant differences in the amount of breakthrough bleeding between the two groups.*

133. The study's results were described in an abstract submitted to the 43rd Annual Meeting of the Society for Gynecologic Investigation, held March 20-23, 1996 in Philadelphia, Pennsylvania. The authors were listed as L.M. Schenk, R.W. Whitcomb, G.D. Hodgen, and F.D. Anderson. The abstract disclosed that the study included 30 women participants who were taking Loestrin 1/20 active tablets for 25 days straight. The abstract was later published in the Journal of the Society for Gynecologic Investigation on or around March 20, 1996.

c. The PTO focused on the amount of ethinyl estradiol in the prior art and whether the invention decreased breakthrough bleeding.

134. On February 5, 1996, the patent examiner issued a Notice of Allowability for all claims. After two supplemental amendments to ostensibly correct mathematical errors, the '394 patent was issued in September 1996.

135. During examination, the patent examiner focused on two issues: (i) the amount of ethinyl estradiol and norethindrone acetate in oral contraceptives disclosed in the prior art; and (ii) whether the invention decreased breakthrough bleeding.

136. First, the examiner focused on whether the prior art included oral contraceptives

with similarly low amounts of ethinyl estradiol and norethindrone acetate. The examiner observed that prior art (specifically, the Craft reference) disclosed a contraceptive regimen with 50 µg of ethinyl estradiol and 3 mg of norethindrone acetate. The examiner also observed that another prior art reference (EPO 253,607) reference disclosed a contraceptive composition in which 15 µg of ethinyl estradiol are administered with progestin daily and a 24-day dosing regimen. The examiner initially concluded that Craft and the EPO references rendered all claims obvious.

137. In response, the applicants represented that commercially available oral contraceptive combination formulations contain at least 30 µg of ethinyl estradiol. (In truth, Loestrin 1/20, publicly available since the 1970s, contained 20 µg of ethinyl estradiol.) The applicants then reminded the examiner that their invention reduced the incidence of breakthrough bleeding:

[T]he claimed regimen leaves the patient with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 mcg EE (Craft uses 50 mcg) and a regimen of 21 dosing day plus a 7-day pill free interval. With the claimed method, although there are more treatment days per year at say 20 mcg EE per day, the total drug exposure on a yearly basis remains significantly below the amount in an estrogen/progestin combination oral contraceptive which contains 30 or more mcg EE daily. In contrast to Craft, the present invention employs a lower estrogen dosage which does not participate in this contraceptive efficacy but instead *controls unscheduled bleeding*.

138. Second, after being redirected by the applicants, the examiner turned to whether the invention in fact unexpectedly reduced the included of breakthrough bleeding. The examiner again rejected the claims because the amount of ethinyl estradiol disclosed in the claims is similar to that disclosed in Craft, and because the applicants haven't shown that it was

unexpected that decreasing the amount of ethinyl estradiol reduces the incidence of breakthrough bleeding:

The applicant's remarks have been considered but are unpersuasive. Claim 1 recited a possible dosage of 35 mcg of estrogen which is only 15 mcg lower than the 50 mcg dosage taught by Craft et al. *It has not been demonstrated that a dosage regimen different by only 15 mcg less of estrogen has unexpected contraceptive and reduced breakthrough bleeding results.*

2. Warner Chilcott, through its executives, knew the '394 patent is invalid and/or unenforceable.

139. By the time Warner Chilcott listed the '394 patent in the Orange Book, Warner Chilcott knew that the '394 patent was invalid and/or unenforceable.

a. The '394 patent is unenforceable.

140. The '394 patent is unenforceable in light of the misrepresentations and omissions made to the PTO during the prosecution of the '394 patent.

141. The applicant's failure to disclose the failed human study was material. The human study showed that there was no reduction in the incidence of breakthrough bleeding associated with the claims of the '394 patent. The '394 patent would not have issued otherwise. Hodgen's omission and misrepresentations were made with knowledge that they were false and misleading, and with the specific intent that the PTO rely on the monkey study and issue a patent. There is no other reasonable explanation for the failure to report a failed human study that the inventor personally conducted. The failed study was intentionally withheld because it undercut patentability.

142. Warner Chilcott knew that Hodgen's unsuccessful study in women had not been disclosed to the PTO during prosecution of the '394 patent.

143. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

144. In 1993, while EVMS's patent application was pending, Hodgen sent a letter proposing a "technology transfer agreement" with Parke Davis. Hodgen explained to Roger Boissonneault (then the Vice President of Female Health Care at Parke Davis, owned by Warner Lambert, and now Warner Chilcott's CEO) why Hodgen believed that Parke Davis should pay EVMS for the "technology" used in the human subject study. Warner Chilcott's CEO and President was thus aware of Hodgen's human study, and presumably the negative results of that study, in 1993.

145. [REDACTED] an agreement between EVMS and Warner Lambert. [REDACTED] an assignment of EVMS's interest in the patent application and any resulting patents to Warner Lambert. The assignment was dated October 2, 1994, over a year before the '394 patent issued.³³

146. Warner Lambert was acquired by Pfizer in 2000. Galen Holdings plc acquired the '394 patent from Pfizer in March 2003 at the same time that it acquired the entire Loestrin franchise. In July 2004, Galen Holdings changed its name to Warner Chilcott.

147. The '394 patent applicants made materials misrepresentations and omissions to the PTO. But for those omissions, the '394 patent would not have issued. And Warner Chilcott and Boissonneault knew this at the time Warner Chilcott listed and then later enforced the '394 patent.

³³ The assignment was not recorded until January 19, 2000.

b. The '394 patent is obvious.

148. Separate and apart from whether the '394 patent is unenforceable due to misrepresentations, the '394 patent is invalid due to obviousness.

149. For the invention disclosed in the '394 patent to be patentable, it must either (1) reflect an amount of ethinyl estradiol and/or norethindrone acetate that were not disclosed in the prior art or (2) actually provide a method for decreasing the incidence of breakthrough bleeding. These are the two issues the examiner focused on during prosecution.

150. If the reduction in breakthrough bleeding is not read as a limitation on the claims presented, then the only novel thing about the claimed invention is the amount of ethinyl estradiol and norethindrone acetate disclosed in the claims. But Loestrin 1/20 contains the specific estrogen and progestin compounds recited in the claims of the '394 patent, in the claimed amounts and in the claimed weight ratios.

151. The difference between Loestrin 1/20 and the purported "invention" is that the '394 patent contemplates taking the active tablets in Loestrin 1/20 for 23 to 25 days (instead of 21 days). But the prior art taught combination oral contraceptives that were given for more than 21 days.

152. Warner Chilcott knew that its own Loestrin 1/20 (commercially available since the late 1970s) contained an amount of ethinyl estradiol and norethindrone acetate that fell within the range of value described in the claims of the '394 patent. Warner Chilcott also knew that Loestrin 1/20 had been commercially available since the late 1970s.

153. Warner Chilcott knew that prior art taught giving oral contraceptives for longer than 24 days well before Hodgen's applied for the '394 patent.

154. Based on the prior art, including the references cited by the examiner, it was obvious to administer active tablets containing low amounts of estrogen and progestin for more than 21 days.

155. The prior art teaches that a seven day tablet-free period leads to follicular development, which can lead to pregnancy. The prior art proposes to provide improved suppression of follicular development by using a 24-day regime of active tablets in oral contraceptive products while incrementally increasing the progestin.

156. The prior art teaches that a seven day tablet-free interval may be associated not only with diminished contraceptive efficacy, but also symptoms of estrogen withdrawal such as migraine headaches.

157. The prior art teaches that the incidence of breakthrough bleeding might, theoretically, be reduced by giving an additional combination tablet in each cycle.

158. There are examples in the prior art of other 24 day regimes that are safe and effective. One of ordinary skill would thus have expected that administering a combination of estrogen and progestin for 23-25 days, or specifically for 24 days, would be safe and effective.

159. The prior art suggests that the seven day tablet-free interval could be shortened to achieve additional benefits, such as reduced risk of follicular development, improved contraceptive efficacy, (theoretically) reduced breakthrough bleeding, and relief from certain symptoms of estrogen withdrawal such as migraine headaches. One skilled in the art would be motivated to reduce the number of tablet-free days by administering additional active tablets.

c. Warner Chilcott knew that Loestrin 24 does not decrease the incidence of breakthrough bleeding.

160. To the extent that a reduction in the incidence of breakthrough bleeding is read as a claim limitation, the '394 patent fares no better.

161. First, Hodgen's human study reflects no statistically significant reduction in the rates of breakthrough bleeding.

162. Second, the FDA concluded that Loestrin 24, the commercial embodiment of the '394 patent, did not actually reduce the incidence of breakthrough bleeding.

163. In January 2005, Boissonneault became CEO and President of Warner Chilcott.

164. Warner Chilcott submitted the NDA for Loestrin to the FDA in April 2005.

165. After reviewing the data from the Loestrin 24 investigational new drug study ("IND"), the FDA concluded that, "for the most part, there were not statistically significant or clinically meaningful differences across the 2 treatment groups in term of any parameters of bleeding that were examined." The FDA noted that "the findings of Study PR-0393 do not support the Applicant's hypothesis that 3 additional days of active treatment (*i.e.*, extending the active treatment period from 21 days to 24 days during each 28 day cycle) would reduce the incidence of intracyclic bleeding."

166. The FDA observed that there was a trend toward a greater percentage of subjects in the Loestrin 24 group not having monthly withdrawal bleeding. (Again, withdrawal bleeding is distinct from intracyclic/breakthrough bleeding or spotting.)

167. The FDA noted that even though the data had not shown that Loestrin 24 had a lower incidence of breakthrough bleeding than Loestrin 1/20, the drug should nonetheless be eligible for approval if it was both safe and effective for the prevention of pregnancy.

168. On February 17, 2006, the FDA approved Loestrin 24 as a method of contraception in women.

169. The FDA warned Warner Chilcott that it could not conclude that Loestrin 24 was superior to Loestrin 1/20, and that the label could not include any comparative claims.

C. Warner Chilcott files sham litigation against generics to delay generic entry.

1. Warner Chilcott sues Watson for allegedly infringing the '394 patent.

170. Because the '394 patent claims only a narrow method (*i.e.*, three extra days of tablets) of using active ingredients that have been employed for decades as oral contraceptives, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 long before the expiration of the '394 patent. The generic manufacturers believed that they could obtain a court ruling that the '394 patent was either invalid and unenforceable or not infringed by their products.

171. On or about June 19, 2006, Watson notified Warner Chilcott that Watson had filed ANDA 78267 in order to market a generic version of Loestrin 24. Watson's notice letter included a paragraph IV certification that the commercial manufacture, use and/or sale of its generic Loestrin 24 product would not infringe any valid claim of the '394 patent.

172. On July 28, 2006, Warner Chilcott sued Watson in the United States District Court for the District of New Jersey,³⁴ alleging that Watson's generic Loestrin 24 product would infringe the '394 patent. Warner Chilcott sued in order to delay generic competition for as long as possible. Simply by filing the case, Warner Chilcott prevented Watson from obtaining FDA approval to market generic Loestrin 24 for at least two-and-a-half years – regardless of whether Warner Chilcott's case had any merit. The 30-month stay would expire on December 19, 2008.

173. During the litigation, Watson challenged the validity and enforceability of the '394 patent, as well as Warner Chilcott's infringement allegations. Watson conducted discovery supporting a host of defenses focusing on: (i) the enforceability of the '394 patent; (ii) the validity of the '394 patent; and (iii) the weakness of Warner Chilcott's infringement allegations.

³⁴ *Warner Chilcott Co. v. Watson Pharms., Inc.*, No. 06-cv-3491 (D.N.J.).

174. On January 23, 2008, Watson filed an amended answer and counterclaim.³⁵

175. Watson argued invalidity and noninfringement. Watson asserted that the claims of the '394 patent were invalid under one or more of 35 U.S.C. § 102 (novelty; prior art), § 103 (obviousness), and § 112 (specification; written description).

176. Watson alleged that the '394 patent was unenforceable in view of equitable doctrines, including inequitable conduct, common law fraud, and unclean hands. Watson alleged that the applicants for the '394 patent, including the inventor, counsel, and others substantially involved in its prosecution, breached their duty of good faith and candor to the PTO (37 C.F.R. § 1.56 and common law) by intentionally misrepresenting material facts, failing to disclose material information, and submitting false information to the PTO with the intent to deceive.

177. Watson alleged the following:

- a. All claims of the '394 patent are unenforceable due to inequitable conduct.
 - i. The applicants intentionally concealed from the PTO a public use of the claimed invention that occurred more than one year before the filing date.
 - ii. The applicants intentionally made false statements to and withheld material information from the PTO concerning the amount of estrogen in prior art oral contraceptives.
 1. The applicants knew that prior art oral contraceptives contained 20 µg of ethinyl estradiol but stated to the PTO that all commercial U.S. oral contraceptives contained at least 30 µg of ethinyl estradiol.
 2. The applicants knew that prior oral contraceptives exposed women to as little as 5.5 mg estrogen but stated to the PTO that their claimed regimen of up to twice as much estrogen exposed women to less.
 - iii. The applicants intentionally withheld prior art teaching an extended regimen of oral contraceptives (more than 21 days) for purportedly enhanced efficacy, including the Molloy reference.

³⁵ The FDA's medical review of the Loestrin 24 NDA was not available to Watson at the time. The approval package was not posted online until March 24, 2008.

- b. Claims 1 and 7-12 of the '394 patent are obvious over the Loestrin Fe 1/20 prior art product in view of various references teaching the shortening of the pill-free interval, Upton, [REDACTED].
 - i. [REDACTED].
 - 1. [REDACTED].
- c. Claims 1 and 7-12 of the '394 patent are invalid as lacking written description, best mode, and enablement under 35 U.S.C. § 112.
- d. Claims 1, 7-8, and 10-12 of the '394 patent are invalid as anticipated under 35 U.S.C. § 102(a) by public use of the claimed method in 1993 in the human study.
- e. The claims of the '394 patent are not infringed by Watson's ANDA.
 - i. [REDACTED].
 - ii. [REDACTED].

178. According to Watson, the claims of the '394 patent were invalid because simply extending the regimen of a well-known prior art product by several days, as is taught in the literature and was practiced by women, was obvious.

179. A reasonable pharmaceutical company in Warner Chilcott's position could not realistically expect to succeed on the merits of its infringement suit against Watson. If litigated to a decision on the merits, the '394 patent would be adjudged invalid and/or unenforceable (for the reasons given above).

180. To prevent Watson's generic product from coming to market, Warner Chilcott would have had to defeat each of Watson's arguments regarding invalidity and unenforceability and prove that Watson's product actually infringed the '394 patent.

181. Warner Chilcott faced a substantial battle. Watson was attacking the only patent providing any coverage for Loestrin 24 – a then \$200 million-a-year drug – on three separate fronts: invalidity, unenforceability, and non-infringement. Discovery had revealed that Warner Chilcott – via its CEO – had learned about the unsuccessful EVMS study in women back in 1993. The FDA’s newly-released medical review for Loestrin 24 confirmed that, on the basis of the data Warner Chilcott provided to the FDA, Loestrin 24 did not significantly reduce the incidence of breakthrough bleeding. Hodgen’s misrepresentations and omissions ensured that Warner Chilcott could not enforce the ’394 patent even if it was infringed. And prior art, including Loestrin 1/20, rendered the patent obvious.

182. For the reasons Watson alleged, and in light of the defects in the ’394 patent described elsewhere in this complaint, Warner Chilcott would have lost the patent infringement suit if it had been litigated to conclusion. So Warner Chilcott decided to pay Watson to settle the patent litigation.

2. Warner Chilcott and Watson enter into a reverse payment settlement agreement.

183. Having stayed FDA approval of Watson’s generic Loestrin 24 application by filing the patent infringement claim against Watson, Warner Chilcott decided to terminate the case just as the 30-month stay was set to expire on or about January 2009.

184. On January 15, 2009, Warner Chilcott and Watson filed a stipulation of dismissal. The parties settled before they briefed, and before the Court finally decided, the substantive issues of invalidity, unenforceability, and infringement.

185. As the Supreme Court explained in *Actavis*, a brand and generic company can settle without reverse payments by simply agreeing on an entry date, one that reflects the underlying strengths or weakness of the patent suit. Here, given that Warner Chilcott’s suit was

objectively baseless, any settlement would have yielded an entry date much earlier than the delayed date purchased by Warner Chilcott in the reverse payment agreement being challenged here.

186. Warner Chilcott opted not for a procompetitive agreement with Watson but instead entered into an anticompetitive agreement where Warner Chilcott unlawfully paid Watson to withdraw its challenges to the validity and enforceability of the '394 patent and delay its introduction of generic Loestrin 24 until just six months before the expiration of the '394 patent.

187. On or about January 12, 2009, Warner Chilcott and Watson entered into a reverse payment settlement agreement (the "Watson agreement"). Pursuant to that agreement, Warner Chilcott ended its '394 patent litigation against Watson, and Watson dropped its counterclaims against Warner Chilcott. At the time of the unlawful agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the claims.

188. Under the Watson agreement, Watson agreed to delay launching its generic Loestrin 24 product until the earliest of: (i) January 22, 2014; (ii) 180 days before a date on which Warner Chilcott grants rights to a third party to market a generic version of Loestrin 24 in the United States; or (iii) the date on which another generic version of Loestrin 24 enters the market.

189. As the quid pro quo for Watson's agreement to drop its challenge to the '394 patent and to delay marketing its generic Loestrin 24, Warner Chilcott agreed to pay Watson substantial sums, in several forms, as set forth herein.

190. All of these payments had substantial value to Watson, and Watson could not have obtained any of these payments even if it had won the patent litigation against Warner

Chilcott.

191. Warner Chilcott made these payments in exchange for Watson's agreement to delay generic competition to Loestrin 24 for more than four years (or earlier under certain circumstances). Absent Watson's agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to make these payments.

192. These payments far exceed the costs of continuing to litigate the settled patent infringement litigation. Well established literature concludes that litigation of a patent infringement suit of this nature, from complaint to verdict, costs between \$6 million and \$10 million. Warner Chilcott's future expected litigation costs at the time of the settlement with Watson were much less than that because, among other reasons, the patent case had been pending for years.

a. The no-AG agreement.

193. The principal component of the Watson agreement was Warner Chilcott's promise not to market, supply or license an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing its generic. Absent the Watson agreement, Warner Chilcott had the incentive and ability to launch an authorized generic version of Loestrin 24 upon entry of a competing generic version of Loestrin 24, and would have done so. Indeed, Warner Chilcott has marketed authorized generic versions of several of its other branded drugs, including its oral contraceptive, Dovonex. Avoiding competition from an authorized generic was a huge financial benefit to Watson.

194. Calculating the size of the payment represented by Warner Chilcott's promise not to launch an authorized generic (the no-AG promise or agreement) for at least six months after Watson's own delayed generic entry in January 2014 involves simple arithmetic using readily available inputs. The calculation is performed by comparing the dollar sales Watson would have

expected to obtain when forced to compete against Warner Chilcott's authorized generic, against the dollar sales Watson would have expected to get when free from Warner Chilcott's authorized generic because Warner Chilcott promised not to launch its authorized generic for six months. The difference is Warner Chilcott's payment to Watson from the no-AG promise. The price and unit effects of generic competition and authorized generics have been extensively studied by academics and the FTC,³⁶ and so a reasonably approximate calculation may be made from publicly available data even before discovery.

195. The generic substitution rate during the first six months of generic competition (that is, the percentage of brand sales that would switch to the generic in the first six months after the generic becomes available) is about 78% (taking the mean between 72% and 85%). The generic price discount (*i.e.*, the percentage below the pre-generic-entry brand price at which the generic sells) during the first six months after generic entry is at least 10% (although it can be higher), when there is just one generic available. According to a study sponsored by PhRMA, the brand drug company trade group, generic prices are an additional 16% lower when an authorized generic is available alongside the first filer, compared with when an authorized generic is absent. According to a study performed by the FTC, an authorized generic takes approximately 50% of unit sales from the first generic during the first six months. Using these basic numbers – 78% generic substitution within six months, the 10% price discount with one generic and 26% discount with two, and an authorized generic taking 50% of unit generic sales – the no AG payment to Watson can be plausibly calculated using simple arithmetic.

196. To estimate Watson's revenues from selling generic Loestrin 24 during the first six months of generic competition without competition from Warner Chilcott's AG, one starts

³⁶ See FTC Pay-for-Delay Study; FTC 2011 AG Study.

with Loestrin 24's annual (*i.e.*, 12-month) branded sales and divides by two to get its sales for six months. As of the time of defendants' agreement, Loestrin 24 was a \$200 million-a-year drug. Half of that (six months) is \$100 million. Though sales were growing and, as a result, sales when Watson launched in 2014 would be expected to be significantly larger, we will use 2009 sales to develop a minimum estimate. Using a conservative 78% generic substitution rate, and a conservative 10% price discount, Watson would expect to earn approximately \$70.2 million in generic sales in six months freed from competition from an authorized generic.

197. To estimate Watson's expected revenues from selling generic Loestrin 24 during the first six months *with* competition from an AG, one starts again with \$100 million in branded Loestrin 24 sales for six months, and the same generic substitution rate, but a generic price discount of 26% (to account for the price effect of the authorized generic) rather than 10%. This means total generic sales (Watson's plus an AG) would be expected to be \$57.72 million over the first six months of generic competition, because of the price-decreasing effect of an AG. Watson would get just half of those sales (because it would split unit sales with the AG, 50/50), so Watson would earn just \$28.86 million.

198. Thus, the difference between Watson's generic Loestrin 24 sales over the first six months of generic competition under a no AG promise (\$70.2 million) compared with an AG (\$28.86 million) is \$41.34 million. This is the estimated minimum payment Watson expected from Warner Chilcott from just Warner Chilcott's no-AG promise (made without benefit of discovery and using conservative assumptions).

199. Even using the conservative \$41.34 million estimate, the no-AG payment is far more than average total patent litigation costs for a Hatch-Waxman patent case, to say nothing of the costs remaining in the patent litigation here. A recent survey by the Association of

Intellectual Property Lawyers of America estimated that the median total cost of patent infringement litigation associated with ANDA filings under the Hatch-Waxman Act was just \$6 million.³⁷ Warner Chilcott and Watson reached their no-AG deal more than two years into their patent litigation. Warner Chilcott instituted suit in July of 2006 and the settlement agreement challenged in this case was reached in January of 2009. The litigation costs Warner Chilcott avoided are likely significantly lower than \$6 million. But even using the \$6 million figure, and even using the \$41.34 million estimate for the minimum size of the no-AG payment, the no-AG payment here was approximately seven times Warner Chilcott's avoided litigation costs, and so is plainly a large payment under *Actavis*.³⁸

200. The defendants here undoubtedly studied and calculated the effects of generic competition for Loestrin 24, both on the brand's sales and the price of the drug, and the effect of the presence or absence of an authorized generic. The 2011 FTC AG Study, for example, obtained data from numerous brand and generic drug companies (including Warner Chilcott and Watson) about the effects of authorized generics.³⁹ The AG Study confirmed that, as a matter of standard business practice, both brand and generic companies calculate the financial effects of the presence or absence of an authorized generic. For brand name companies, the AG Study concluded:

The brand-name firms' keen interest in the revenues arising from AGs and their intense concern with any impact of the AG on branded sales are reflected in their extensive forecasting and sales analysis documents. Virtually every brand-name company in the

³⁷ American Intellectual Property Lawyers Association, *2013 Report of the Economic Survey*, at 34 (2013). This figure represents branded drugs with sales "at risk" of at least \$25 million; for less valuable branded drugs, the median litigation costs were less than \$6 million.

³⁸ See 133 S. Ct. at 2236 (explaining that defendants may be able to defend a reverse payment by showing that it "may amount to no more than a rough approximation of the litigation expenses saved through the settlement" and was made to avoid those costs).

³⁹ FTC 2011 AG Study at ii, 7-8 & app. C.

study that had marketed an AG produced multiple forecasts and revenue analyses in response to the FTC Special Orders. The forecasts were incorporated into different phases of company decision making, including decisions to market an AG, select an external distributor, determine launch timing, and project how much to manufacture. After launch of an AG, companies closely monitored actual revenues, price, and market share to facilitate adjustments based on market conditions.⁴⁰

201. Similarly, documents produced by the generic companies:

. . . confirm that the introduction of an AG during the exclusivity period substantially erodes the expected profitability of the ANDA *In fact, various sales and pre-launch forecasts indicate that generic firms routinely assume the presence of an AG, and weave that consideration, along with assumptions about market size, substitution rates, price erosion, and the likely number of competitors, into their projections of sales and profitability of the ANDA-generic drug during the exclusivity period and beyond.*⁴¹

202. Thus, discovery here is very likely to reveal similar internal analyses by defendants themselves examining the financial effects of the presence or absence of an authorized generic version of Loestrin 24. Such internal analyses can then be used to further refine the quantification of the no-AG payment here.

b. Warner Chilcott protects Watson's purported exclusivity from additional generic competition.

203. In addition to the no-AG promise, Warner Chilcott agreed not to grant a license to any other manufacturer to produce a generic version of Loestrin 24 – whether under Warner Chilcott's NDA or under any ANDA – until at least 180 days after Watson entered the market, thus functionally recreating the 180-day exclusivity Watson had lost. Warner Chilcott thus guaranteed to Watson a period of 180 days of exclusivity as the only generic Loestrin 24 on the market (absent another generic manufacturer entering following a 30-month stay of FDA

⁴⁰ *Id.* at 68 (footnote omitted).

⁴¹ *Id.* at 81-82 (footnote omitted).

approval or obtaining a court order permitting such entry). Because Watson forfeited its entitlement to the 180-day exclusivity period under the Hatch-Waxman Act by failing to obtain tentative FDA approval to market generic Loestrin 24 within 30 months of submitting its ANDA in April 2006, the contractual exclusivity granted by Warner Chilcott had substantial value to Watson and precluded generic competition at the expense of the direct purchaser class plaintiffs and other class members.

204. In a February 19, 2013 earnings call, Paul Bisaro, Watson/Actavis's CEO, President, and Director, represented that Watson retained 180-day exclusivity on Loestrin 24. Because the FDA had determined that Watson was not entitled to the statutory exclusivity period under the Hatch-Waxman Act, Bisaro could only have been referring to exclusivity resulting from Watson's agreement with Warner Chilcott.

c. Side deals disguise substantial additional payment.

205. In addition to the no-AG agreement and Warner Chilcott's promise not to grant a license to any other generic manufacturer during Watson's de facto 180-day exclusivity period, the Watson agreement also provided substantial additional compensation in the form of two side deals announced contemporaneously with the settlement of the patent litigation relating to Loestrin 24. These side deals include: (i) a transfer to Watson of exclusive rights to market and sell a new conceptive product called Generess Fe⁴² (the "Generess deal"), memorialized through a patent license agreement and finished product supply agreement, each of which was on terms highly advantageous to Watson, and (ii) a co-promotion agreement relating to Warner Chilcott's contraceptive product Femring (the "Femring deal").

206. Due to their nature and timing, the side deals were part and parcel of the Watson

⁴² As with Loestrin, the "Fe" is regularly dropped.

agreement and provided Watson with substantial additional compensation for agreeing to delay market entry. Indeed, these types of deals between brand and generic companies, consummated at the same time as settlement of seemingly unrelated patent litigation provide a means to confer payment under the guise of an independent business arrangement. Such deals between brand and generic companies are rarely seen outside of the reverse payment settlement context because generic firms are not obvious and efficient alternative suppliers for a brand company due to their smaller promotional teams and limited research and development and manufacturing capabilities. Thus these side deals are merely cover for a brand's purchase of additional freedom from competition. The deals at issue here are no exception.

(1) The Generess deal.

207. Through the Generess deal, Warner Chilcott effectively relinquished the rights to its chewable oral contraceptive Generess for a modest supply price and limited royalty payment structure. Watson is now the NDA holder for Generess, a product developed by Warner Chilcott. This transfer of value from Warner Chilcott to Watson has no rational explanation other than to provide additional compensation to Watson for delaying its generic Loestrin 24.

208. [REDACTED] deal, Watson was granted an exclusive license to [REDACTED]

[REDACTED] Generess Fe [REDACTED]

[REDACTED]. Watson was responsible for the commercialization of Generess Fe (*e.g.*, sales, marketing, distribution).

209. The Generess deal provided that Warner Chilcott would be responsible for

210. Under the terms of the Generess deal, Watson got to keep [REDACTED]

[REDACTED]
[REDACTED].

211. The Generess deal provided compensation to Watson that was well in excess of the fair value of the costs and services undertaken by it pursuant to the deal. The deal effectively provided payment to Watson in the form of the right to retain [REDACTED] as partial exchange for its agreement to delay generic entry for Loestrin 24. The economic terms of the Generess deal do not reflect those of an arm's length, stand-alone transaction between two parties in the position of these companies, but instead substantially are weighed in favor of Watson to provide additional consideration for its agreement to drop the Loestrin 24 patent challenge.

212. Generess has generated significant sales since its launch in April 2011. According to the most recent data from IMS National Sales Perspectives ("NSP") (a recognized and standard source of data on pharmaceutical prescriptions, sales, and prices), from the time it was launched until generic entry in April 2015, Generess generated sales of over \$268 million. Sales after generic entry through February 2016 are nearly \$17 million. Total sales attributable to Generess from its launch in April 2011 through February 2016 have been in excess of \$285 million.

213. Both Warner Chilcott and Watson expected Watson to [REDACTED]

[REDACTED] and Watson has in fact [REDACTED]
[REDACTED]

(2) The Femring deal.

214. The Femring deal provided substantial additional compensation to Watson for agreeing to delay generic entry. Pursuant to that agreement, Warner Chilcott, [REDACTED]

██████████ granted Watson ██████████ to promote Femring in the United States from January 9, 2009 ██████████

215. In exchange for its promoting Femring, Warner Chilcott agreed to compensate Watson as follows:

- a. [REDACTED]
[REDACTED];⁴³ and
- b. [REDACTED]

216. The Femring deal provided substantial compensation to Watson that was, in and of itself, in excess of the fair value of Watson's cost of performance. Conservatively, the co-promotion agreement provided Watson with [REDACTED] in consideration for its promise to agree to delay entry of generic Loestrin: [REDACTED]

217. Discovery is likely to reveal information concerning the various components of the Watson agreement that will allow the direct purchaser plaintiffs to more accurately quantify the payments to Watson in exchange for delayed generic entry. Absent Watson's agreement to delay entry of generic Loestrin 24, Warner Chilcott would not have agreed to: (i) refrain from launching, or granting a license to others to launch, an authorized generic Loestrin 24 during Watson's first 180 days of marketing; (ii) grant Watson a license to market generic Loestrin 24 beginning January 22, 2014; (iii) designate Watson as a co-promoter of Femring; (d) grant

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Watson an exclusive license to market and sell Generess; (iv) guarantee Watson 180 days of exclusivity, which it had otherwise forfeited, to market a generic version of Loestrin 24; and/or (v) grant the price and/or other terms that it did under those provisions of the Watson agreement.

218. To avoid competition, maintain its monopoly in the Loestrin 24 market and continue to reap monopoly profits, Warner Chilcott agreed to pay Watson what amounts to tens of millions of dollars. The large payment from Warner Chilcott to Watson had no justification other than to keep Watson's AB-rated generic version of Loestrin 24 off the market for nearly five years. These payments far exceed Warner Chilcott's costs of continuing to litigate the settled patent infringement litigation.

3. Warner Chilcott sues, and then settles with, Lupin.

219. As the first filer, Watson had an opportunity to earn 180 days of exclusivity under the Hatch-Waxman amendments. At the time Watson filed its ANDA, of course, subsequent ANDA filers could not have predicted that Watson would ultimately forfeit its 180-day exclusivity. If Watson had obtained an order finding the '394 patent invalid or unenforceable, other generic manufacturers would have benefitted from that ruling without having to incur patent litigation costs.

220. On or about July 30, 2009, six months after the announcement of the agreement between Warner Chilcott and Watson, Lupin Pharmaceutical, Inc., and/or Lupin Ltd. ("Lupin") notified Warner Chilcott that it had filed ANDA 91398 for the purpose of marketing generic versions of Loestrin 24. Lupin's notice letter included a paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 patent.

221. On or about September 9, 2009, Warner Chilcott sued Lupin for alleged

infringement of the '394 patent in the United States District Court for the District of Delaware.⁴⁴

Lupin answered the complaint on October 21, 2009, and alleged special defenses, including invalidity of the '394 patent and non-infringement.

222. Warner Chilcott filed the case against Lupin without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Lupin from the market for 30 months. Had the case proceeded to a litigated conclusion, Warner Chilcott would have lost.

223. During discovery, Lupin, like Watson before it, uncovered facts supporting a host of defenses that cast serious doubt on: (i) the enforceability of the '394 patent; (ii) the validity of its claims; and (iii) the strength of Warner Chilcott's infringement allegations.

224. Lupin alleged the following:

a.

[REDACTED]

i.

[REDACTED]

ii.

[REDACTED]

b. The '394 patent is invalid as anticipated by

[REDACTED]

i.

[REDACTED]

⁴⁴ *Warner Chilcott Co. v. Lupin Ltd.*, C.A. No. 09-673 (D. Del.).

- c. Based on the publicly available allegations made by Watson in the earlier patent infringement suit (only), the '394 patent may be invalid for anticipation by prior public use.
- d. The '394 patent is obvious in light of prior art, [REDACTED].
- e. The '394 patent is unenforceable for inequitable conduct before the PTO, including:
 - i. Failure to disclose [REDACTED].
 - ii. Misrepresenting the amount of estrogen contained in commercially available products.
 - 1. Hodgen likely knew that a prior art commercial product contained less than 30 µg of ethinyl estradiol, contrary to the applicants' representation that all U.S. contraceptives then contained at least 30 µg ethinyl estradiol.
 - 2. [REDACTED].
 - 3. The applicants did not disclose the Molloy reference titled "‘Missed Pill’ Conception, Fact or Fiction," [REDACTED].

225. Had Lupin obtained a final judgment invalidating the '394 patent, it could have launched its generic Loestrin 24. To make sure this did not happen, and to ensure that Watson could retain its faux 180 days of market exclusivity created by the Watson agreement, Warner Chilcott settled with Lupin, the second ANDA filer for Loestrin 24.

226. On or about October 10, 2010, before the close of fact discovery and before the court could issue any substantive rulings, Warner Chilcott entered into an agreement with Lupin (the "Lupin agreement") and dismissed the case.

227. Pursuant to the Lupin agreement, Lupin agreed to drop its challenge to the '394 patent (including its counterclaims) and to delay entry of its generic version of Loestrin 24 until July 22, 2014, the month that the '394 patent expires and six months after Watson could launch.

228. The Lupin agreement granted Lupin a non-exclusive license covering Femcon Fe, another branded oral contraceptive manufactured by Warner Chilcott, which permitted Lupin to begin marketing an authorized generic version of Femcon Fe, supplied by Warner Chilcott, in the United States beginning on the earlier of (i) 180 days after Teva Pharmaceutical Industries, Ltd (the first filer with respect to Femcon Fe) entered the market with a generic equivalent to Femcon Fe, or (ii) January 1, 2013. Pursuant to the Lupin agreement, Lupin in fact entered the market with generic Femcon Fe in October 2011, and since that time has made substantial sales of that product. But for the Lupin agreement, Lupin could not have begun making generic Femcon Fe sales until the end of the 30-month stay in February 2012.

229. The Lupin agreement also gave Lupin the contingent right to purchase and sell in the United States a generic version of Asacol 400 mg (a branded treatment for inflammatory bowel disease), to be supplied by Warner Chilcott, if a generic version of Asacol 400 mg is launched by another generic manufacturer in the United States.

230. [REDACTED]

[REDACTED].

231. Warner Chilcott's settlement with Lupin delayed market entry of generic Loestrin 24 and ensured that Watson would have 180 days of *de facto* exclusivity upon its launch of generic Loestrin 24.

232. Warner Chilcott and Lupin continue to adhere to the Lupin agreement.

233. On October 28, 2015, the FDA approved Lupin's ANDA 091398 for generic Loestrin 24 Fe. Lupin launched its generic Loestrin 24 Fe product under the name Blisovi 24 Fe in late 2015.

4. Warner Chilcott sues, and then settles with, Mylan.

234. On or about April 20, 2011, six months after the announcement of the agreement

between Warner Chilcott and Lupin, Mylan notified Warner Chilcott that it had filed ANDA 202742 for the purpose of marketing generic versions of Loestrin 24. Mylan's notice letter included a paragraph IV certification that the commercial manufacture, use, and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 patent.

235. On or about June 2, 2011, Warner sued Mylan for alleged infringement of the '394 patent in the United States District Court for the District of New Jersey.⁴⁵ Mylan answered the complaint on August 29, 2011 and asserted counterclaims and special defenses, including invalidity of the '394 patent and non-infringement.

236. Warner Chilcott filed the case against Mylan without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Mylan from the market for 30 months. Had the case proceeded to a litigated conclusion, Warner Chilcott would have lost.

237. During discovery, Mylan, like Watson and Lupin before it, uncovered facts supporting a host of defenses that cast serious doubt on: (i) the enforceability of the '394 patent; (ii) the validity of its claims; and (iii) the strength of Warner Chilcott's infringement allegations. The case continued through claim construction and was set for a bench trial to commence on August 12, 2013. Mylan submitted its trial brief on July 24, 2013.

238. Mylan alleged the following:

- a. Mylan will not directly infringe the '394 patent [REDACTED]
- b. [REDACTED]
- c. The claims of the '394 patent, [REDACTED], are invalid for obviousness in light of Loestrin 1/20, [REDACTED]

⁴⁵ *Warner Chilcott Co. v. Mylan Inc.*, C.A. No. 3:11-cv-3262 (D.N.J.).

[REDACTED]

- i. Loestrin 1/20 includes all limitations of claim 1 except for the duration of treatment;
- ii. [REDACTED]
- iii. [REDACTED]
- iv. [REDACTED]
- d. Secondary considerations of non-obviousness do not override a determination of obviousness based on primary considerations.
 - i. [REDACTED]
 - ii. [REDACTED]
 - iii. [REDACTED]
- e. All claims of the '394 patent are invalid for lack of written description and enablement. [REDACTED]

239. During Markman proceedings, Warner Chilcott and Mylan disputed the construction of the phrase “which is characterized by a reduced incidence of breakthrough

bleeding.” Mylan took the position that this phrase was a claim limitation meaning that an invention must actually reduce the incidence of breakthrough bleeding to be covered by the ’394 patent. Warner Chilcott – given the FDA’s definitive conclusions – could not argue that Loestrin 24 actually reduced the incidence of breakthrough bleeding with a straight face. So Warner Chilcott took the position that this phrase was not a claim limitation.

240. The court’s choice of claim construction would have no impact on the ultimate outcome of the litigation. Either way, Warner Chilcott would lose. If the court chose Mylan’s construction, the ’394 patent would not cover Loestrin 24; Warner Chilcott would stand no realistic chance of prevailing in proving that Mylan’s product infringed a valid patent covering Loestrin 24. If the Court chose Warner Chilcott’s construction, the day of reckoning would have been postponed, but the patent would have been ultimately held invalid as obvious. Without the feature of reducing breakthrough bleeding, the only remaining features of the invention were the amounts of hormones given (disclosed in Loestrin 1/20), the ratios of the hormones given (disclosed in Loestrin 1/20), and the longer-than-21-day period of administration (disclosed in multiple pieces of prior art).

241. On April 8, 2013, the Mylan court issued a claim construction decision, adopting Warner Chilcott’s position.

242. On July 24, 2013, Mylan submitted a pretrial brief.

243. To continue to prevent generic entry by enforcing the ’394 patent, Warner Chilcott would have had to defeat each of Mylan’s arguments regarding invalidity and unenforceability and prove that Mylan infringed the ’394 patent. Warner Chilcott instead decided to protect its monopoly by entering an agreement with Mylan under which Mylan agreed to withdraw its challenges to the validity and enforceability of the ’394 patent and delay its

introduction of generic Loestrin 24.

244. Had Mylan obtained a final judgment invalidating the '394 patent, it would have caused the entry into the market of generic Loestrin 24 delayed by the Watson agreement. Instead, to make sure this did not happen, and to ensure that Watson could retain 180 days of market exclusivity, Warner Chilcott entered a settlement and license agreement with Mylan, the third ANDA filer for Loestrin 24, to drop its patent challenge and stay out of the market until after Watson was permitted to enter the market pursuant to the Watson agreement.

245. On or about July 29, 2013, just weeks before a bench trial was scheduled to commence, Warner Chilcott entered into a non-competition agreement (in the form of a settlement and license agreement) with Mylan and the case was subsequently dismissed. Pursuant to the Warner Chilcott and Mylan agreement, Mylan agreed to drop its challenge to the '394 patent and to delay entry of its generic version of Loestrin 24 until July 22, 2014, the month that the '394 patent expired.

246. Warner Chilcott entered the agreement with Mylan for delayed market entry of generic Loestrin 24 to ensure that Watson would have 180 days of exclusivity upon its launch of generic Loestrin 24 – as Warner Chilcott and Watson agreed to do in the Watson agreement.

247. Warner Chilcott and Mylan continue to adhere to their agreement.

248. On October 30, 2014, the FDA approved Mylan's ANDA 202742 for generic Loestrin 24 Fe. Mylan launched its generic Loestrin 24 product on the same day.

249. Warner Chilcott has delayed generic entry in order to extend and protect its Loestrin 24 monopoly as long as possible.

5. Other Loestrin 24 generics enter the market.

250. On May 20, 2013, Actavis announced that it was acquiring Warner Chilcott.

251. On October 10, 2013, Actavis completed its acquisition of Warner Chilcott. As

part of Actavis's acquisition of Warner Chilcott, on September 27, 2013, Actavis entered into Consent Orders with the FTC that required Actavis to divest four pharmaceutical products including Loestrin 24 and its generic equivalents.

252. On September 30, 2013, Amneal Pharmaceuticals, LLC ("Amneal") announced that it had entered into a deal with Actavis to acquire the four pharmaceutical products including Loestrin 24. Amneal acquired Watson's right to launch its generic Loestrin 24 pursuant to the Watson agreement. On November 8, 2013, Amneal announced that it would launch Loestrin 24 under the name Lomedia 24 Fe, and on or about January 6, 2014, Amneal began selling Lomedia 24 Fe. Lomedia 24 Fe is still manufactured by Watson and is labeled and distributed by Amneal.

253. As a result of the no-AG agreement that Warner Chilcott had entered into with Watson, when Amneal (as successor to Watson) launched generic Loestrin 24 in January 6, 2014, it faced no price competition from an AG. As a result, generic prices were predictably higher than they otherwise would have been. Thus, as a direct and foreseeable result of the defendants' conduct to delay additional generic competition, plaintiffs suffered overcharges on their purchases of Amneal's generic Loestrin 24 (manufactured by Watson).

254. On December 1, 2014, the FDA approved two ANDAs for generic Loestrin 24 Fe: ANDA 090293, submitted by Qualitest Pharmaceuticals, a subsidiary of Endo International plc ("Qualitest"), and ANDA 090938, submitted by Barr Pharmaceuticals, Inc., a division of Teva Pharmaceutical Industries, Ltd. ("Teva"). Qualitest launched its generic Loestrin 24 Fe product under the name Gildess 24 Fe on or about January 22, 2015. Teva launched its generic Loestrin 24 Fe product under the name Junel Fe 24 on or about June 8, 2015.

255. On February 18, 2015, the FDA approved ANDA 202994 for generic Loestrin 24 Fe submitted by Novast Laboratories Ltd. Novast launched its generic Loestrin 24 Fe product

under the name Larin 24 Fe on or about June 12, 2015.

D. Warner Chilcott’s agreements with Watson, Lupin, and Mylan require continuing performance in order to inflict continuing overcharges on direct purchasers.

256. The anticompetitive effects of the reverse payment settlement agreement between Warner Chilcott and Watson stem not merely from the execution of the agreements but also from the continued performance of those agreements over the past four years. For the defendants’ anticompetitive agreement to be effective, each must each actually take steps to abide by the agreements. That ongoing performance and conduct includes, but is not limited to the following:

- a. Warner Chilcott must actually pay Watson according to the terms of the Watson agreement;
- b. Warner Chilcott must prosecute and delay later ANDA filers’ attempts to launch a generic version of Loestrin 24;
- c. Watson must actually stay off the market through January 22, 2014;
- d. Warner Chilcott has to cut deals to settle with, later generic filers (including Lupin and Mylan) to protect the entry date Warner Chilcott and Watson agreed to;
- e. Warner Chilcott and Watson must prevent a court ruling on the merits of the ’394 patent; and
- f. Warner Chilcott’s continuing to overcharge direct purchasers for *years* following the Watson agreement.

E. Warner Chilcott “hops” the market to Minastrin 24.

1. With the prospect of generic competition looming in 2014, Warner Chilcott implemented another aspect of its anticompetitive scheme. Before manufacturers of generic Loestrin 24 could begin marketing their products, Warner Chilcott reformulated Loestrin 24 into another product, Minastrin 24, with the purpose and effect of preventing generic Loestrin 24 from being substitutable for the “new” product at the pharmacy counter.

257. The “product hop” that Warner Chilcott implemented from Loestrin 24 to

Minastrin 24 had no safety or efficacy benefits for patients. The insignificant tweaks that Warner Chilcott made to Loestrin 24 ensured that generic Loestrin 24 would not be AB-rated to Minastrin 24 and therefore not substitutable for Minastrin 24 at the pharmacy counter.

Pharmacists cannot fill a prescription for Minastrin 24 with generic Loestrin 24. Warner Chilcott made the insignificant modifications to Loestrin 24 for the sole purpose of impairing generic competition.

1. The FDA approves Minastrin 24 and Warner Chilcott pulls Loestrin 24 off the market.

258. On July 9, 2012, Warner Chilcott submitted NDA 203667, for an oral contraceptive comprised of 24 active norethindrone acetate (1 mg)/ethinyl estradiol (20 mg) tablets and four inactive ferrous fumarate tablets, which it later sold under the brand name Minastrin 24 Fe. The FDA approved Minastrin 24 ten months later, on May 8, 2013.

259. Minastrin 24 is Loestrin 24 with two changes: First, in the FDA's words, Warner Chilcott made "insignificant manufacturing changes" to the active tablets and added spearmint and a sweetener to the inactive pills (only). Second, Warner Chilcott's proposed labeling referred to the pill as chewable and instructed women to chew and then swallow the pill.

260. There is no medical reason for women to take the inactive pills. Women regularly throw out the pack after they have taken the last active pill and do not take the inactive pills. Making the inactive pills more palatable conveys no benefit. In fact, the labeling for Loestrin 24 refers to the inactive tablets as "reminder" pills. It instructs patients to "THROW AWAY" the reminder pills they missed if they forget to take one.

261. According to the FDA, the active pills in Loestrin 24 and Minastrin 24 are essentially identical. "The only difference in the tablet proposed in [the Minastrin] NDA are the markings;" "even though the identical tablets (except for debossing (Fn 1)) are used for this drug

product, the dosage form will be a **chewable tablet** instead of a tablet.”⁴⁶ Warner Chilcott did not do anything to make the active Loestrin 24 pills palatable; it added no sweeteners or flavors to the active pills. Warner Chilcott simply changed the label to say that women could chew the pills.

262. According to the FDA:

The [Minastrin 24] drug product is a tablet that contains 1 mg NA and 0.020 mg (20 µ) EE. It is identified in this NDA as WC3040-1F tablet. It is the same formulation as Loestrin® 24 FE tablets, approved as an oral tablet in NDA 21-871. The only different in the tablets proposed in this NDA are the markings.

Elsewhere, the FDA states:

It should be noted that even though the identical tablets (except for debossing⁴⁷) are used in this drug product, the dosage form will be a **chewable tablet** instead of a tablet.⁴⁸

The FDA also says:

With the exception of tablet debossing and insignificant manufacturing changes, the to-be-marketed NA and EE tablets are the same as the NA and EE tablets of Loestrin® 24 Fe.

The FDA states:

The NA and EE tablets of the proposed product have the same components, composition, doses, and dosing regimen as the NA and EE tablets of Loestrin® 24 Fe. The difference between the new product WC3040 (also referred to as WC3040-1F tablets) and approved Loestrin® 24 Fe is the method of use. The NA and EE tablets in the new product may be chewed and swallowed or swallowed

⁴⁶ Emphasis in original.

⁴⁷ A debossed marking is sunken into the surface of the material. The FDA states, “The chewable tablet will be debossed with ‘535’ and is referred to as formulation WC3040-1F by the sponsor.”

⁴⁸ Emphasis in original.

whole⁴⁹ compared to the NA and EE tablets in the Loestrin® 24 Fe product that are swallowed whole.

According to the FDA:

[The Minastrin 24] ferrous fumarate (FF) tablets are non-hormonal and do not serve a therapeutic purpose. The inactive FF tablets contain a sweetener (one separate component) and a flavoring (one separate component) as part of the formulation. The WC3040-1F tablet contains no sweetener or flavoring.

263. Minastrin 24 consists of the same components, composition, doses, and dosing regimen of Loestrin 24 Fe and is indicated for the same use. That is, both drug products are used only for the prevention of pregnancy, and both consist of 24 active white tablets (each containing 1 mg norethindrone acetate and 20 µg ethinyl estradiol) as well as four brown placebo or “reminder” tablets (each containing 75 mg Fe fumarate). According to the FDA, “with the exception of tablet debossing and insignificant manufacturing changes, the proposed drug product [Minastrin 24] is identical to approved Loestrin 24 Fe.”

264. Warner Chilcott obtained FDA approval for Minastrin 24 by establishing bioequivalence to Loestrin 24. It conducted no new clinical studies to demonstrate that Minastrin 24 was any more safe or effective than Loestrin 24. Warner Chilcott relied on the previous Phase 3 study of Loestrin 24 tablets for the demonstration of safety and efficacy. Minastrin 24 thus has an identical side effect profile to Loestrin 24. Minastrin also does not result in any increased rate of patient compliance and is otherwise no better than Loestrin 24 in preventing pregnancy.

265. The notable yet minor difference between the two drug products is simply their

⁴⁹ Some portions of the FDA’s review state that Minastrin 24 may be chewed and swallowed or swallowed. But Minastrin 24’s original labeling, proposed by Warner Chilcott, instructed patients and doctors that “The tablet should be chewed and swallowed.”

method of use. The original label for Minastrin 24 instructs that the tablets should be chewed and swallowed; compared to the label for Loestrin 24 that indicates the tablets are to be swallowed whole. Later, Warner Chilcott amended the Minastrin 24 label to say that the pills could be chewed or swallowed. This difference is clinically meaningless to patients. But because Minastrin 24 is considered a different formulation than Loestrin 24, it cannot be substituted at pharmacies for generic Loestrin 24.

266. Loestrin 24 patients by and large were neither in need of nor interested in a birth control pill that they can chew. For those women who preferred to chew their birth control pills, doctors had been advising them they could do so for years. And if making pills chewable were a meaningful benefit for a substantial number of women, Warner Chilcott could have supplemented or amended its Loestrin 24 NDA to reflect that the product was chewable.

267. Loestrin 24 tablets posed no difficulty in swallowing for women. Individuals who find it difficult to swallow tablets frequently cite size as the reason. Yet Loestrin 24, Minastrin 24, and most other oral birth control products, are merely 6 mm in diameter – considered ideal for, and among the smallest of, all oral medications. The size of a tablet is typically not a source of complaint until the tablet becomes greater than 13 mm – more than double the size of Loestrin 24. Suffice it to say, there was no need to reformulate Loestrin 24 into a chewable tablet based on its size.

268. Complaints about swallowing are associated more with children and the elderly – two patient populations who do not take oral contraceptives. Loestrin 24 and Minastrin 24 are not indicated for use before a female's first menstrual period, nor are they indicated for use by the geriatric patient population.

269. Indeed, most patients *prefer* swallowing tablets to chewing tablets, with one

study showing the preferences at more than a nine to one margin. Patients complain that chewing tablets creates fragments that stick to the gums or mouth recesses and leaves some patients uncertain as to whether they in fact ingested all of the needed medicine.

270. Doctors had instructed patients who had difficulty swallowing oral contraceptives to chew their pills for years before Minastrin 24 was approved. Earlier chewable forms of oral contraceptives show no significant bioavailability/bioequivalence differences in the rate and extent of absorption of the active ingredients.

271. Warner Chilcott effectively forced consumers that had been using Loestrin 24 to switch to the chewable tablet.

2. Warner Chilcott forces patients to switch by withdrawing Loestrin 24 from the market and cannibalizes Loestrin 24 sales.

272. Warner Chilcott launched Minastrin 24 on July 1, 2013 and immediately set its detail force to convincing doctors to switch their prescriptions from Loestrin 24 to Minastrin 24.

273. On or around August 2013, with generic entry for Loestrin 24 looming just months away, Warner Chilcott strategically withdrew Loestrin 24 from the market. Warner Chilcott offered no safety or efficacy concerns to justify discontinuing Loestrin 24. Warner Chilcott did not remove existing Loestrin 24 supplies from the market but instead ceased manufacturing and distributing Loestrin 24. Warner Chilcott used the announcement of the discontinuance of Loestrin 24 as a tactic to coerce doctors who otherwise would have continued to prescribe Loestrin 24 to switch to Minastrin 24.

274. Loestrin 24 and Minastrin 24 are not AB-rated and therefore are not substitutable for each other at the pharmacy counter. Thus, a prescription for Minastrin 24 cannot be filled with generic Loestrin 24.

275. Instead, Warner Chilcott insisted to pharmacies, doctors, and patients that

Minastrin 24 is the replacement to which patients should switch. This forced patients who had become stabilized on the 24-day regimen and who were tolerating it well to switch to Minastrin 24.

276. Demonstrating that there is no difference between Loestrin 24 and Minastrin 24, other than the lack of an AB-rating, Warner Chilcott later changed the Minastrin 24 label to say that women could chew *or swallow* the pills. On June 6, 2014 – after Minastrin 24 was awarded a new formulation exclusivity based on the fact that it was chewable, six months after Warner Chilcott withdrew Loestrin 24 from the market, and the very same day Warner Chilcott sued Lupin over Minastrin 24 – Warner Chilcott changed its label to say that women could chew *or swallow* Minastrin 24 pills.

277. But for the defendants' unlawful conduct, AB-rated generic versions of Loestrin 24 would have entered the market long before entry of Minastrin 24, which would have resulted in most Loestrin 24 prescriptions having been converted to AB-rated generic versions of Loestrin 24 long ago, and long before the switch to Minastin 24.

278. It is well known in the industry that, where a brand manufacturer successfully converts the market before the generics enter the market, the generics will make far fewer sales or no sales. Warner Chilcott knew that if it switched the market before generic entry in 2014, the generics would make very few sales because, by that time, Warner Chilcott would have all but eliminated the prescription base. Warner Chilcott's product hop was designed to deprive the generics of the cost-efficient means of competing for sales.

279. After launching Minastrin 24 in July 2013, Warner Chilcott employed its army of sales force detailers to cannibalize Loestrin 24 prescriptions, *i.e.*, to aggressively switch them to Minastrin 24. Warner Chilcott bolstered its detailers' efforts by eliminating all promotion of

Loestrin 24. Warner Chilcott switched all of these promotional efforts to Minastrin 24 instead of Loestrin 24, which it had announced would be discontinued.

280. Data confirm that in the months after the launch of Minastrin 24 in July 2013, nearly 100% of Minastrin 24 sales came from patients who previously had been taking Loestrin 24.

281. Warner Chilcott knew that if it switched the prescription base to Minastrin 24 before January 2014, those prescriptions would not be switched back to Loestrin 24 even after generic versions of that product entered the market. Patients stay on a particular oral contraceptive for long periods of time. And oral contraceptive patients like to stay on a single drug once they find one that works. Patients prefer not to risk unnecessary symptoms or complications by switching drugs.

282. Warner Chilcott's product hop caused enormous concern among women who had previously used Loestrin 24. Many patients were concerned and confused about why they now had to chew a product that they had previously swallowed. Only after succeeding in its scheme to impair generic competition did Warner Chilcott change the label for Minastrin 24 to say women could chew or swallow the pills.

3. Warner Chilcott's motive in switching the market was to impair generic competition.

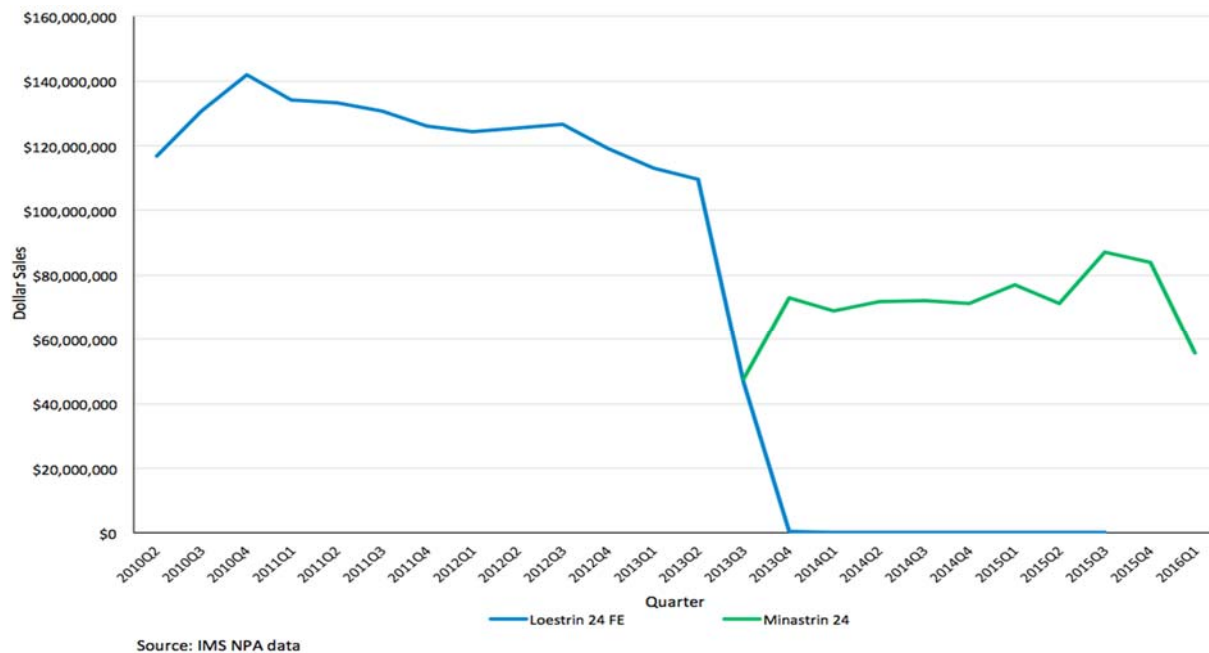
283. The exclusionary motive and effect of Warner Chilcott's product hop is confirmed by the fact that the hop made economic sense for Warner Chilcott only because it had the effect of impairing generic competition. Its decisions to incur the extra costs (and suffer the revenue losses) associated with the change in dosage form from Loestrin 24 to Minastrin 24 was economically rational only because the change had the exclusionary effect of impairing generic competition. But for the impact on generic competition, Warner Chilcott would not have

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invested the resources necessary to tweak and cannibalize Loestrin 24 because doing so would have been economically irrational.

284. Warner Chilcott experienced a loss of sales due to the product hop from Loestrin 24 to Minastrin 24. Warner Chilcott knew when it was planning the product hop that its combined sales of Loestrin 24 and Minastrin 24 would be far less than its sales of Loestrin 24 before the hop. Figure 4 shows Warner Chilcott's wholesale dollar sales, and that Warner Chilcott's projections were correct:

Figure 4. Loestrin 24 & Minastrin 24 Wholesale Dollar Sales



285. Warner Chilcott incurred substantial costs in order to garner these reduced sales. Warner Chilcott spent significant sums in order to develop Minastrin 24, obtain a patent that purportedly protected it, gain FDA approval, and promote the product.

286. If the product hop did not have the effect of impairing generic competition, the hop would have been a money-losing proposition for Warner Chilcott. The product hop made

economic sense for Warner Chilcott solely because the hop did have the effect of impairing generic competition. Warner Chilcott's investments in reformulating and cannibalizing the sales of Loestrin 24 were not investments in improving products and helping patients; they were investments in impairing competition.

4. Warner Chilcott's delay in marketing Minastrin 24 confirms the purpose and effect of impairing generic competition.

287. If Minastrin 24 were a valuable improvement over Loestrin 24 and not merely a means of impairing generic competition, Warner Chilcott would have introduced Minastrin 24 as early as possible. A valuable improvement would have helped Warner Chilcott compete against other branded oral contraceptives in non-price dimensions. Indeed, Instead, Warner Chilcott chose to delay marketing Minastrin 24 for more than four years.

288. Warner Chilcott knew that it could obtain a three-year marketing exclusivity for Minastrin 24 by submitting a study showing that it had no worse a safety profile than Loestrin 24.⁵⁰

289. Warner Chilcott first submitted its NDA (022365) for Minastrin 24 on May 20, 2008. On January 12, 2009, just months away from expected FDA approval of the reformulation, Warner Chilcott withdrew its request for FDA approval. The FDA noted that Warner Chilcott withdrew the request for approval "for business reasons."

290. The only apparent "business reason" was that three days earlier, on January 9, 2009, Warner Chilcott had agreed to pay Watson to delay entering the market with generic Loestrin 24 until January 2014. Warner Chilcott's purpose in tweaking the product was to impair generic competition. So, having bought a delay in generic competition, Warner Chilcott

⁵⁰ 21 U.S.C. § 355(j)(5)(F)(iii).

no longer had an immediate need to then pursue approval of the tweaked product.

291. Warner Chilcott re-submitted the same NDA on September 12, 2010. Warner Chilcott then withdrew it a second time on November 15, 2010 – a month after Lupin agreed to delay marketing its generic Loestrin 24 until July 2014. Having secured the delayed entry it bought from Watson, Warner Chilcott no longer had an immediate need to reformulate the product.

292. Warner Chilcott re-submitted the Minastrin 24 NDA on July 9, 2012 and pursued it to completion only when the delay it secured from generic entry of Loestrin 24 was finally coming to an end. Mindful of the need to convert the market from Loestrin 24 to Minastrin 24 before generic Loestrin 24 entered the market, Warner Chilcott obtained FDA approval for Minastrin 24 in May 2013. Warner Chilcott then implemented the product hop beginning in July 2013 – in just enough time to convert the market before the Watson generic Loestrin 24 was scheduled to enter in January 2014.⁵¹

5. Warner Chilcott's product hop substantially impaired generic competition.

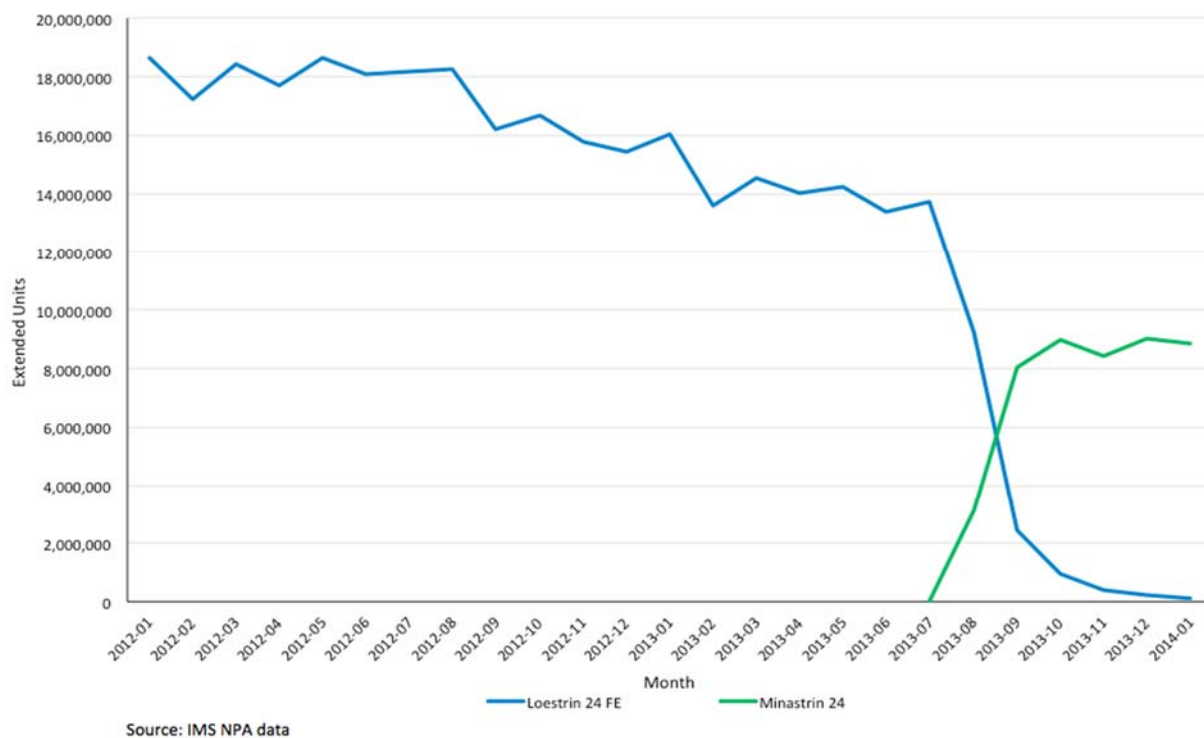
293. Warner Chilcott's product hop and withdrawal of Loestrin 24 from the market was enormously successful for Warner Chilcott. Had Warner Chilcott not converted the market from Loestrin 24 to Minastrin 24, 100% of the prescriptions written for Warner Chilcott's oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 µg) tablets and four ferrous fumarate tablets would have been AB-rated to and subject to automatic substitution

⁵¹ In the early 2000s, Warner Chilcott successfully prosecuted a patent for a chewable, palatable oral contraceptive (the '050 patent). Warner Chilcott listed this patent in the Orange Book as covering Minastrin 24 and at least two other chewable oral contraceptive formulations. In November and December 2011, Warner Chilcott (but not Watson) separately sued Mylan and Lupin for allegedly infringing the '050 patent in the United States District Court for the District of New Jersey. The generics argued the patent was invalid and/or unenforceable, primarily due to obviousness. On April 29, 2014, the court held that the claims of the '050 patent are obvious and, therefore, invalid. The court's opinion is sealed. But, based on the appellate record, the district court apparently held that a person skilled in the art would have arrived at the "invention" of the '050 patent via multiple obviousness combinations, including a chewed paper pill known since the 1970s.

with generic Loestrin 24.

294. Instead, Warner Chilcott successfully converted virtually all Loestrin 24 prescriptions to Minastrin 24 before Watson’s generic entered in January 2014. As Figure 5 shows, Warner Chilcott’s anticompetitive conduct ensured that there were few sales of branded Loestrin 24 by January 2014:

Figure 5. Sales of Loestrin 24 & Minastrin 24 (in Retail Extended Units)

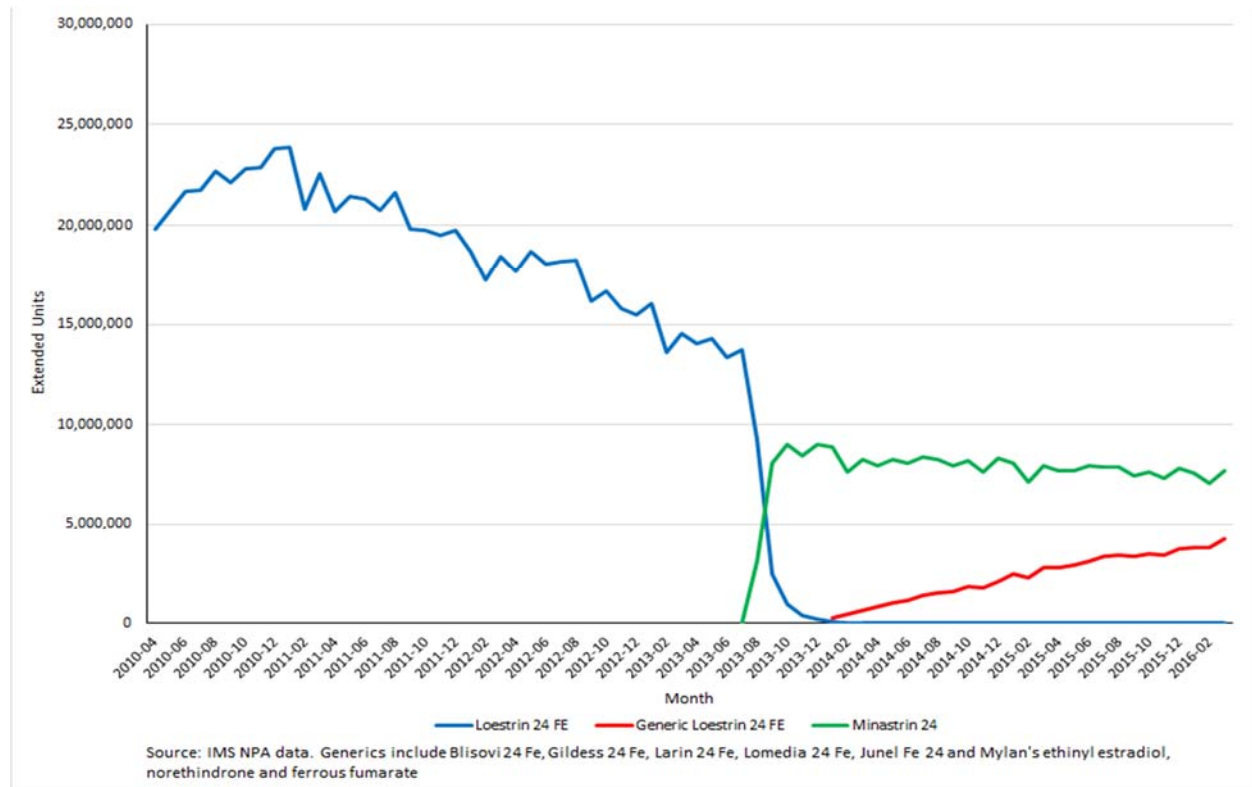


295. Decades ago, with the passage of the Hatch-Waxman amendments and the state drug substitution laws, to overcome the price disconnect in pharmaceutical markets, Congress and every state provided for the distribution of generic drugs through automatic substitution at the pharmacy counter. Such substitution is generic manufacturers’ cost-efficient means of competing. Warner Chilcott’s product hop and withdrawal of Loestrin 24 from the market deprived generic manufacturers of their cost-efficient means of competing, and more

importantly, deprived purchasers and consumers of the benefits of that competition.

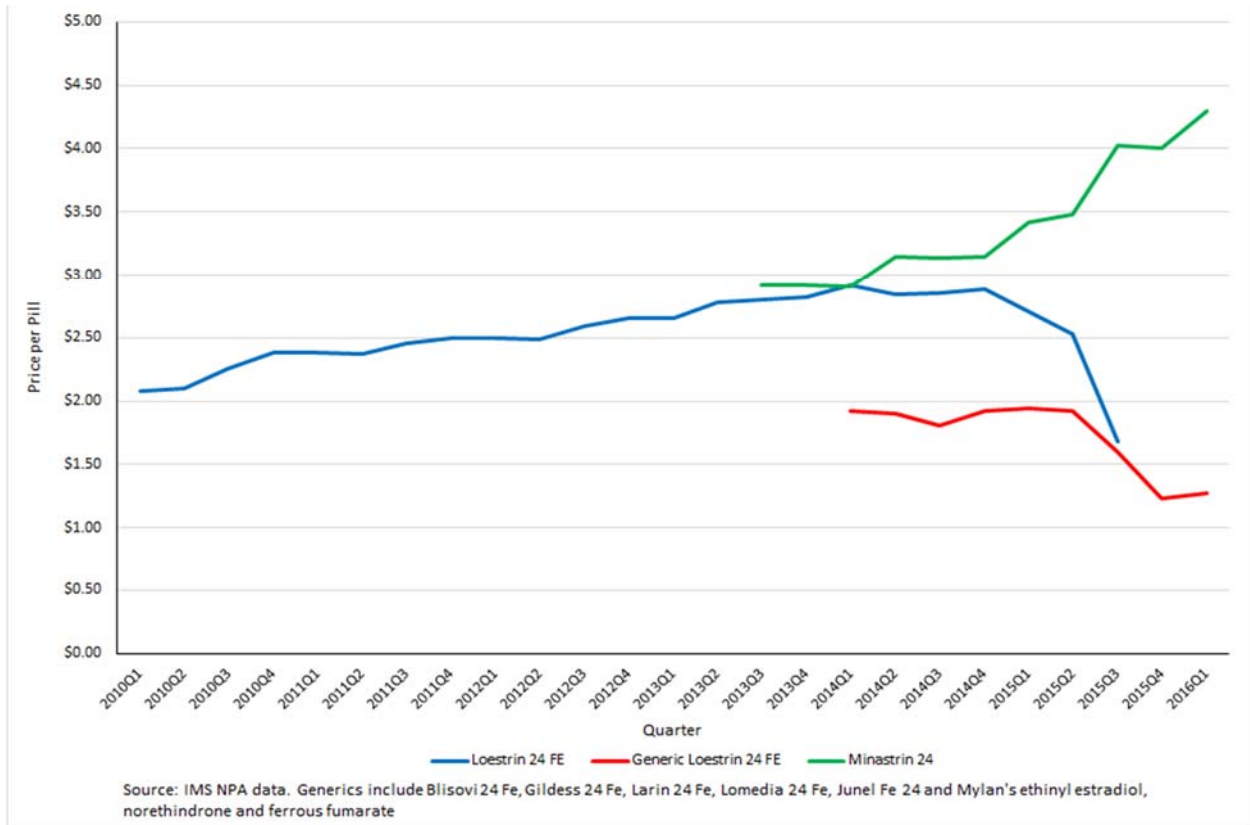
296. The following charts show unit sales and prices of Loestrin 24 (brand and generic) and Minastrin 24. As shown by Figure 6, the hard switch from Loestrin 24 to Minastrin 24 caused near total unit sales of Loestrin 24 to be replaced by Minastrin 24 in the month preceding the entry of AB-rated generic Loestrin 24. As shown by Figure 7, replacement of Loestrin 24 with Minastrin 24 (a branded drug that could not be automatically substituted by a generic) enabled Warner Chilcott to continue increase prices.

Figure 6. Sales of Loestrin 24, Generic Loestrin 24, and Minastrin 24 (in Retail Extended Units)



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Figure 7. Loestrin 24, Generic Loestrin 24, & Minastrin 24 Wholesale Price per Pill



VI. CLASS ALLEGATIONS

297. The direct purchaser class plaintiffs bring this action as a class action under Fed. R. Civ. P. 23(a) and (b)(3) on behalf of themselves and as representatives of a class defined as follows:

All persons or entities in the United States and its territories who purchased brand or generic Loestrin 24 or Minastrin 24 directly from Warner Chilcott or Amneal at any time during the period September 1, 2009 through and until the anticompetitive effects of the defendants' conduct cease (the "class period").

Excluded from the class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities. Also excluded from the class are educational institutions such as universities and colleges.

298. Members of the class are so numerous that joinder is impracticable. The direct purchaser class plaintiffs believe that there are dozens of class members. Further, the class is readily identifiable from information and records that the defendants and Amneal are required by law to maintain.

299. The direct purchaser class plaintiffs' claims are typical of the claims of the members of the class. The direct purchaser class plaintiffs and all members of the class were damaged by the defendants' same wrongful conduct. Specifically, they paid artificially inflated prices for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 µg ethinyl estradiol) and four ferrous fumarate placebo tablets and were deprived – and are still deprived – of the benefits of competition from cheaper generic versions of Loestrin 24 as a result of the defendants' wrongful conduct.

300. The direct purchaser class plaintiffs will fairly and adequately protect and represent the interests of the class. The direct purchaser class plaintiffs' interests are coincident with, and not antagonistic to, those of the class.

301. The direct purchaser class plaintiffs and the class are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

302. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

303. Questions of law and fact common to the class include:

a. whether the defendants conspired to restrain generic competition to Loestrin 24;

b. whether Watson unlawfully agreed to delay its entry into the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 µg ethinyl estradiol) and four ferrous fumarate placebo tablets, *i.e.*, Loestrin 24 and its AB-rated generic bioequivalents;

c. whether Warner Chilcott paid Watson in exchange for a delay in generic competition for Loestrin 24;

d. whether Warner Chilcott's compensation to Watson was necessary to yield some procompetitive benefit that is legally cognizable and non-pretextual;

e. whether Warner Chilcott entered into agreements with subsequent filers, such as Lupin and Mylan, to protect Warner Chilcott's and Watson's anticompetitive scheme;

f. whether the defendants' challenged conduct suppressed generic competition to Loestrin 24;

g. whether the defendants' challenged conduct harmed competition in the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 µg ethinyl estradiol) and four ferrous fumarate placebo tablets;

h. whether Warner Chilcott possessed market power in the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 µg ethinyl estradiol) and four

ferrous fumarate placebo tablets, *i.e.*, Loestrin 24 and its AB-rated generic bioequivalents and Minastrin 24;

i. whether the relevant antitrust market (if a relevant market must be defined) is the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 µg ethinyl estradiol) and four ferrous fumarate placebo tablets, *i.e.*, Loestrin 24 and its AB-rated generic bioequivalents and Minastrin 24;

j. whether the defendants' activities alleged herein have substantially affected interstate commerce;

k. whether, and to what extent, the defendants' conduct caused antitrust injury to the business or property of the direct purchaser class plaintiffs and members of the class in the nature of overcharges; and

l. the quantum of overcharges paid by the direct purchaser class plaintiffs and the class in the aggregate.

304. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

305. The direct purchaser class plaintiffs know of no special difficulty to be

encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND RELEVANT MARKET

306. At all relevant times Warner Chilcott had monopoly power in the market for oral contraceptives with 24 active tablets containing 1 mg norethindrone acetate and 20 µg ethinyl estradiol and four inactive iron tablets (“Loestrin 24 drugs”) and narrower markets therein, because they had the power to raise or maintain the price of Loestrin 24 drugs at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable.

307. “Loestrin 24 drugs” includes Loestrin 24 and its AB-rated generic equivalents as well as Minastrin 24 and its AB-rated generic equivalents.

308. Warner Chilcott had the ability to control the prices of Loestrin 24 drugs and exclude relevant competitors. Direct evidence demonstrates that: (i) generic versions of each drug would have entered the market at substantial discounts to the brand versions but for the defendants’ anticompetitive conduct; (ii) the gross margin on each drug was at all times at least 60%; and (iii) the defendants never lowered the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs.

309. To the extent that the plaintiffs are required to prove monopoly power by defining a relevant product market, the plaintiffs allege that the relevant product market is the market for oral contraceptives with 24 active tablets containing 1 mg norethindrone acetate and 20 µg ethinyl estradiol and four inactive iron tablets, *e.g.*, Loestrin 24, AB-rated equivalents to that drug, and Minastrin 24 (the “Loestrin 24 drugs”), and narrower markets therein.

310. A small but significant, non-transitory price increase in the price of Loestrin 24 drugs did not cause a significant loss of sales. At competitive prices, Loestrin 24 drugs do not

exhibit significant, positive, cross-elasticity of demand with respect to price with any other oral contraceptive other than AB-rated generic versions of those Loestrin 24 drugs.

311. Warner Chilcott needed to control only Loestrin 24 drugs and their AB-rated generic equivalents, and no other products, in order to maintain the price of the products profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 drugs would render the defendants unable to profitably maintain supracompetitive prices for those products.

312. Warner Chilcott sold branded Loestrin 24 drugs in excess of marginal costs, and in excess of the competitive price, and enjoyed unusually high profit margins.

313. The United States and its territories constitute the relevant geographic market.

314. At all relevant times, Warner Chilcott enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and AB-rated generic substitution laws.

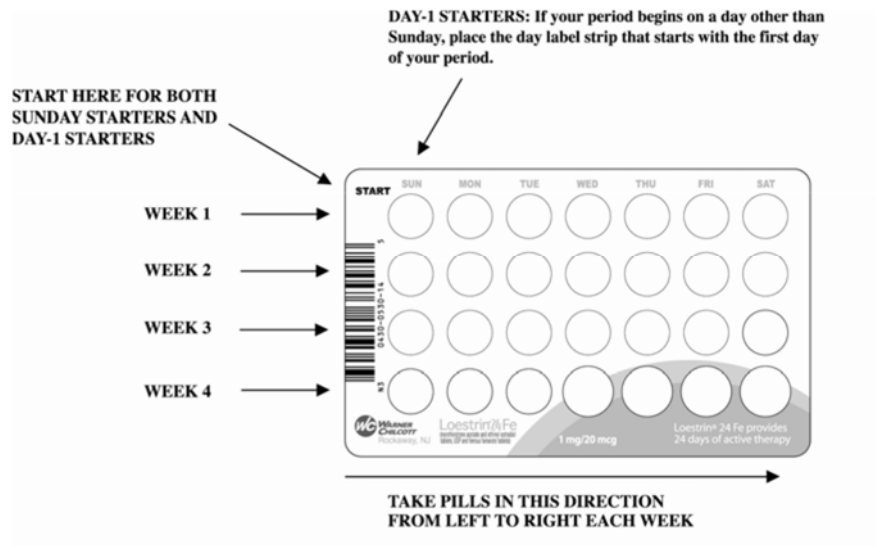
315. At all relevant times, Warner Chilcott's market share in the relevant market was 100%.

316. Loestrin 24 and Minastrin 24 are not reasonably interchangeable with any products other than AB-rated generic versions of Loestrin 24 drugs because Loestrin 24 and Minastrin 24 have different attributes significantly differentiating them from other oral contraceptives and making them unique as against other oral contraceptives. The FDA does not consider Loestrin 24 drugs and other oral contraceptives interchangeable, and there is variation in the dosage of the active ingredients. Oral contraceptives have different chemical compounds and formulations, such as varying amounts of progestin.

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317. Oral contraceptive pills are dispensed in packs, where each pack contains the right number of pills to last for one cycle (28 days). Each pack contains between 21 and 28 pills. Each pill is labeled with either a day of the week (M, T, W, etc.) or the day of the cycle (Day 1, Day 2, Day 3, etc.) when it should be taken.

Figure 8. Loestrin 24 Packaging



318. Some formulations of oral contraceptives have higher failure rates in certain classes of women, and they differ widely in their safety and side-effect profiles. For example,

oral contraceptives differ in the endometrial, progestational, androgenic, and estrogenic activity. The differing efficacy, safety, and side effect profiles of different oral contraceptives play a critical role in doctors' selection of the most appropriate oral contraceptive for a particular patient and a woman's decision to continue taking an oral contraceptive she has found to work well.

319. Price does not drive prescriptions for oral contraceptives. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Loestrin 24, to patients without a prescription written by a doctor. This prohibition introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

320. Warner Chilcott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and aggressively (and sometimes illegally) persuade them to prescribe the manufacturer's products.⁵² These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a

⁵² In fact, Warner Chilcott admittedly instructed its sales representatives to use illegal tactics to increase and maintain its market share. In October 2015, Warner Chilcott pleaded guilty to criminal and civil charges of unlawfully marketing several of its drugs, including Loestrin 24. Among other things, Warner Chilcott violated the federal anti-kickback statute by providing inducements to physicians to prescribe Warner Chilcott's drugs. Warner Chilcott agreed to pay \$102.06 million to the federal government and certain states, resolving claims that its actions caused false claims to be submitted to government health care programs. Warner Chilcott also agreed to pay a criminal fine of \$22.94 million.

comparatively unimportant role in product selection.

321. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drugs, such as oral contraceptives, is made by the physician, not female consumers of these products. Additionally, once the physician and patient find a product that is well-tolerated, it is very unlikely that the patient will switch to a different oral contraceptive based on variations of price of 10% or less.

322. Doctors generally select an oral contraceptive for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price. For clinical reasons, among others, physicians and patients prefer Loestrin 24 to other products designed to prevent pregnancy. Due to, among other reasons, its use and varying ability to prevent pregnancy while causing shorter, lighter periods, Loestrin 24 is significantly differentiated from all products other than AB-rated generic versions of Loestrin 24.

323. The existence of other products designed to prevent pregnancy has not significantly constrained Warner Chilcott's pricing of Loestrin 24 (or its pricing of Minastrin 24).

324. Warner Chilcott needed to control only Loestrin 24 and its AB-rated generic equivalents, and no other products, in order to maintain the price of Loestrin 24 profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 would render Warner Chilcott unable to profitably maintain its current prices of Loestrin 24 without losing substantial sales.

325. Despite the availability of other oral contraceptive products, including lower

priced generics that are not AB-rated to Loestrin 24, sales of Loestrin 24 increased from 2008 to 2011, and the price of Loestrin 24 rose each year. This is in stark contrast to what would have occurred if an AB-rated generic version of Loestrin 24 had come to market. For example, when an AB-rated generic version of Yaz-28, an oral contraceptive sold by Bayer Healthcare, became available in 2010, sales of branded Yaz-28 dropped from a reported \$781 million in 2009, to \$150 million in 2011. The generic version of Yaz-28 was not AB-rated, however, to Loestrin 24 and, thus, not surprisingly, while sales of branded Yaz-28 plunged from 2009 to 2011, sales of branded Loestrin 24 *increased* between 2009 and 2011.

326. At all relevant times, Warner Chilcott has sold Loestrin 24 and Minastrin 24 at prices well in excess of the competitive price.

327. Warner Chilcott had, and exercised, the power to exclude and restrict competition to Loestrin 24, its AB-rated bioequivalents, and Minastrin 24.

328. Warner Chilcott, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

329. The relevant geographic market is the United States and its territories.

330. Warner Chilcott's market share in the relevant market was 100% at relevant times.

VIII. MARKET EFFECTS AND DAMAGES TO THE CLASS

331. But for the anticompetitive conduct alleged above, Watson would have entered the market with its generic Loestrin 24 as early as September 1, 2009, when its ANDA 78267 received final FDA approval. Warner Chilcott would have launched an authorized generic version of Loestrin 24 simultaneously. Lupin, Mylan, and other generic manufacturers would have entered the market with additional generic versions of Loestrin 24 entering thereafter.

332. The defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Loestrin 24 from generic competition.

333. Watson, Lupin, and Mylan have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

334. The defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Loestrin 24, has caused the direct purchaser class plaintiffs and the class to pay more than they would have paid for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 µg) tablets and four ferrous fumarate placebo tablets absent the defendants' illegal conduct.

335. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, virtually all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug.

336. This price competition enables all purchasers of the drug to: (i) purchase generic versions of a drug at substantially lower prices; (ii) purchase generic equivalents of the drug at a lower price, sooner; and/or (iii) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

337. But for the defendants' anticompetitive conduct, the direct purchaser class

plaintiffs and members of the class would have paid less for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 µg) tablets and four ferrous fumarate placebo tablets by: (i) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of more-expensive branded Loestrin 24; (ii) receiving discounts on their remaining branded Loestrin 24 purchases; (iii) purchasing generic Loestrin 24 at lower prices sooner; and (iv) purchasing less expensive generic Loestrin 24 instead of more expensive branded Minastrin 24.

338. Due to the defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (i) launching generic versions of Loestrin 24, and/or (ii) challenging the validity or infringement of the '394 patent in court.

339. Thus, the defendants' unlawful conduct deprived the direct purchaser class plaintiffs and the class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT

340. During the relevant time period, the direct purchaser class plaintiffs and members of the class purchased substantial amounts of Loestrin 24 and Minastrin 24 directly from Warner Chilcott and purchased generic Loestrin 24 directly from Amneal. As a result of the defendants' illegal conduct, the direct purchaser class plaintiffs and members of the class were compelled to pay, and did pay, artificially inflated prices for their oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 µg) tablets and four ferrous fumarate placebo tablets. Those prices were substantially greater than the prices that the direct purchaser class plaintiffs and members of the class would have paid absent the illegal conduct alleged herein, because: (i) the price of Loestrin 24 was artificially inflated by the defendants' illegal conduct, and (ii) the direct purchaser class plaintiffs and class members were deprived of the opportunity

to purchase lower-priced generic versions of Loestrin 24.

341. As a consequence, the direct purchaser class plaintiffs and members of the class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. EFFECT ON INTERSTATE COMMERCE

342. At all material times, Loestrin 24, manufactured and sold by Warner Chilcott, was shipped across state lines and sold to customers located outside its state of manufacture.

343. During the relevant time period, in connection with the purchase and sale of Loestrin 24, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

344. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The defendants' activities were within the flow of, and have substantially affected, interstate commerce.

XI. STATUTE OF LIMITATIONS

345. The direct purchaser class plaintiffs were not injured by the defendants' scheme (and their claims did not accrue) until at least September 1, 2009 – the date on which Watson's ANDA received final FDA approval.⁵³

346. Absent the defendants' conduct, on or after September 1, 2009 a lower cost generic version (and an AG version) of Loestrin 24 would have been available for the direct purchaser class plaintiffs to purchase.

⁵³ The first direct purchaser class action complaint was filed in this district on May 14, 2013. *Am. Sales Co., LLC v. Warner Chilcott Public Ltd. Co.*, No. 13-347 (D.R.I. May 14, 2013), ECF No. 1.

347. Additionally, the defendants fraudulently concealed the terms of the Watson agreement. While the Watson agreement was announced on January 9, 2009, the specific terms of the agreement, including the existence of the reverse payments therein, were not publicly disclosed at that time and prevented the direct purchaser class plaintiffs from immediately discovering their claims.

348. The defendants' conduct has inflicted continuing and accumulating harm upon the direct purchaser class plaintiffs through the present. Each sale of Loestrin 24 to the direct purchaser class plaintiffs caused them a separate injury and constituted an overt act that started the statutory period.

349. Both Warner Chilcott and Watson engaged in overt acts in furtherance of their anticompetitive scheme, including that: (i) Watson Chilcott paid both Watson and Lupin according to the terms of the Watson agreement and the Lupin agreement; (ii) Warner Chilcott prosecuted and delayed later ANDA filers' attempts to launch a generic version of Loestrin 24; (iii) Watson and its successor (Amneal) did not launch their generic Loestrin 24 until January 2014; (iv) Warner Chilcott entered into arrangements with other, later generic filers (including Lupin and Mylan) to protect Watson's entry date; (v) Warner Chilcott and Watson prevented a court ruling on the merits of the '394 patent; (vi) Warner Chilcott hopped the market to more expensive Minastrin 24 to thwart substitution of less expensive Loestrin 24 generics; and (vii) Warner Chilcott continued to overcharge the direct purchaser class plaintiffs for *years* following the Watson agreement.

XII. CLAIMS FOR RELIEF

VIOLATION OF 15 U.S.C. § 2 MONOPOLIZATION (Against Warner Chilcott)

350. The direct purchaser class plaintiffs incorporate by reference the preceding

allegations and paragraphs.

351. At all relevant times, Warner Chilcott possessed substantial market power (i.e. monopoly power) in the relevant market. Warner Chilcott possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

352. Warner Chilcott engaged in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for oral contraceptives with 24 active tablets containing 1 mg norethindrone acetate and 20 µg ethinyl estradiol and four inactive iron tablets.

Warner Chilcott's anticompetitive scheme included the following conduct:

- a. Improperly listing the '394 patent in the Orange Book as covering Loestrin 24 while knowing the patent to be invalid and/or unenforceable (whether due to obviousness, misrepresentations made during prosecution, or both);
- b. Filing sham lawsuits against generic manufacturers of Loestrin 24 without regard for the merits and with intent to delay generic entry;
- c. Paying off Watson to delay entering the market with generic Loestrin 24;
- d. Reformulating Loestrin 24 into Minastrin 24, the sole purpose of which was to render generic Loestrin 24 tablets non-substitutable;
- e. Cannibalizing the sales of Loestrin 24 before generic entry; and
- f. Pulling Loestrin 24 from the market months before expected generic entry;

353. Through the anticompetitive scheme described above, Warner Chilcott willfully maintained and continues to maintain monopoly power in the relevant market using restrictive and exclusionary conduct rather than by providing better products or services, and thereby injured the direct purchaser class plaintiffs and members of the class. Specifically, by denying the direct purchaser class plaintiffs and members of the class the opportunity to purchase drugs in the relevant market at a substantial discount via generic substitutes, Warner Chilcott willfully maintained its monopoly over (and supracompetitive profits in) the relevant market.

354. Warner Chilcott's conscious objective was and is to continue its dominance of the relevant market by and through the anticompetitive scheme described above.

355. Warner Chilcott's anticompetitive scheme harmed competition and purchasers as alleged above.

356. There are no non-pretextual, procompetitive justifications for Warner Chilcott's conduct. Even if there were such a conceivable justification, the anticompetitive effects of the conduct far outweigh any conceivable justification. Further, the anticompetitive scheme was far broader than necessary to achieve any conceivable procompetitive benefit.

357. Warner Chilcott's anticompetitive scheme was the direct and proximate cause of the direct purchaser class plaintiffs' and the class's injuries.

358. The direct purchaser class plaintiffs and the members of the class have been injured in their business or property as a direct and proximate result of Warner Chilcott's anticompetitive conduct. The injuries include: (i) being denied the opportunity to purchase lower-priced generic Loestrin 24 instead of more expensive branded Loestrin 24; (ii) being forced to purchase generic Loestrin 24 at higher prices because of the absence of other generic competition; and (iii) being forced to purchase a more expensive branded Minastrin 24 instead of less expensive generic Loestrin 24. These injuries are the type that the antitrust laws were designed to prevent and flow from that which makes Warner Chilcott's conduct unlawful.

**VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Warner Chilcott and Watson)**

359. The direct purchaser class plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

360. The defendants, Warner Chilcott and Watson, have engaged and continue to

engage in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of section 1 of the Sherman Act, 15 U.S.C. § 1.

361. The unlawful contract, combination, or conspiracy consisted of Warner Chilcott and Watson entering into the Watson agreement, under which Warner Chilcott agreed to pay Watson substantial consideration in exchange for Watson's agreement to delay bringing its generic version of Loestrin 24 to the market. The purpose and effect of this agreement and conduct were, and are, to: (i) allocate 100% of the market for Loestrin 24 products in the United States to Warner Chilcott; (ii) prevent the sale of generic versions of Loestrin 24 in the United States, thereby protecting Loestrin 24 from generic competition for five years or more; (iii) fix, raise, maintain, or stabilize the price at which direct purchasers would pay for Loestrin 24 or its AB-rated generic equivalent at supracompetitive levels; and (iv) allocate 100% of United States generic Loestrin 24 sales to Watson during the first 180 days of generic sales.

362. The Watson agreement harmed the direct purchaser class plaintiffs and the class as set forth above.

363. The Watson agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

364. The agreement between and among Warner Chilcott and Watson and their conduct under the Watson agreement is an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, non-pretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

365. As a direct and proximate result of Warner Chilcott's and Watson's anticompetitive conduct, as alleged herein, the direct purchaser class plaintiffs and the class have been harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

XIII. DEMAND FOR JUDGMENT

WHEREFORE, Ahold and RDC, on behalf of themselves and the class, respectfully request that the Court:

- a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), direct that reasonable notice of this action as provided by Fed. R. Civ. P. 23(c)(2) be given to the class, and declare Ahold and RDC representatives of the class;
- b. Enter joint and several judgments against the defendants and in favor of Ahold, RDC, and the class;
- c. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and
- d. Award Ahold, RDC, and the class their costs of suit, including reasonable attorneys' fees as provided by law.

XIV. JURY DEMAND

366. Pursuant to Fed. Civ. P. 38, the direct purchaser class plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: March 28, 2018

Respectfully submitted,

/s/ Jeffrey B. Pine

Patrick C. Lynch (R.I. Bar No. 4867)

Jeffrey B. Pine (R.I. Bar No. 2538)

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of Direct Purchaser Class Plaintiffs' Third Amended Consolidated Class Action Complaint and Jury Demand to be filed electronically via the Court's CM/ECF system. Those attorneys who are registered CM/ECF users may access these filings, and notice of these filings will be sent to those parties by operation of the CM/ECF system.

Dated: March 28, 2018

/s/ Thomas M. Sobol
Thomas M. Sobol (R.I. Bar No. 5005)